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Date: 20 September 2006 No. of Pages: 93
TO: Examiner Carolyn Brown COMPANY: USPTO
FAX: 571-273-8300
FROM: *Robert W. Mason/cer* DEPARTMENT: Legal
FAX: 210 255 6969 PHONE: 210 255 6271
Message: Re: Application No. 09/458,280
Attorney Docket No.: VAC.331A.US
Technical Center 3700

Dear Ms. Brown:

Per our telephone conversation today, attached please find the following:

1. Filing Receipt 01/24/00
2. Office Action 10/04/00
3. On Petition 08/06/02
4. Notice Regarding POA 08/15/02
5. Office Action 10/21/02
6. Office Action 03/03/03
7. Notice of Non-Recordation 05/22/03
8. Notice of Recordation/Assignment 05/22/03
9. Office Action 11/24/03
10. Notice of Allowance & Fees Due 12/27/04
11. On Petition 02/18/05
12. Notice of Allowance & Fees Due 06/01/05
13. Notice Under 37 CFR 1.251 06/23/06
14. Various Auto-Reply Facsimile Transmission
15. Various Return Postcards

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Mailing:

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San Antonio, Texas 78219-4334

(210) 662-0215

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PTO-109X
(Rev. 6-99)

FILING RECEIPT

COPY



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/458,280	12/10/99	3738	\$760.00	2000.1035	7	10	2

022775

WAYNE J COLTON INC
THE MILAM BUILDING SUITE 1108
115 EAST TRAVIS STREET
SAN ANTONIO TX 78205

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

RICHARD C. VOGEL, SAN ANTONIO, TX; DAVID M. TUMEY,
SAN ANTONIO, TX; SUSAN P. MORRIS, SAN ANTONIO, TX; L. TAB
RANDOLPH, SAN ANTONIO, TX.

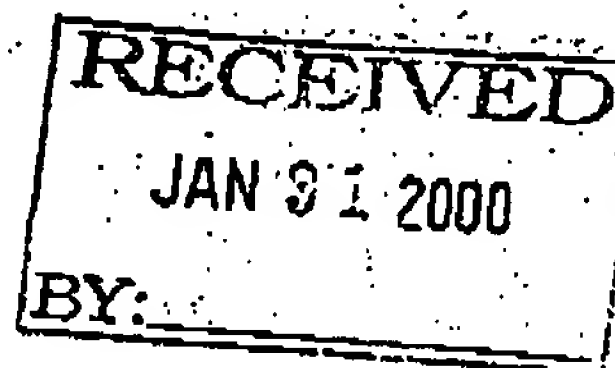
CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A DIV OF 08/903,026 07/30/97
PROVISIONAL APPLICATION NO. 60/053,902 07/28/97

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 01/24/00
TITLE

THERAPEUTIC APPARATUS FOR TREATING ULCERS

PRELIMINARY CLASS: 128



DATA ENTRY BY: BROWN, ROSCOE

TEAM: 03 DATE: 01/24/00

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Sep. 20. 2006 11:58AM

KCI Concepts Inc.

No. 3627 P. 3



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/458,280 · 12/10/99 · VOGEL

R 2000.1035

022775
WAYNE J COLTON INC
THE MILAN BUILDING SUITE 1032
115 EAST TRAVIS STREET
SAN ANTONIO TX 78205

09/12/1004

EXAMINER

DEMILLE, D

ART UNIT

PAPER NUMBER

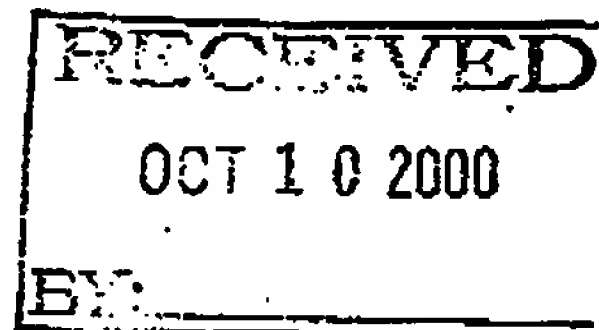
3764

DATE MAILED:

10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Office Action Summary

Application No.

09/458,280

Applicant(s)

Vogel et al.

Examiner

Danton DeMille

Art Unit

3764

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other.

Application/Control Number: 09/458,280
Art Unit: 3764

Page 2

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. In claim 1, it is not clear what is meant by "concurrent with the introduction of said negative pressure". How is the structure of the foot wrap further limited by this language?
3. It is not clear how the limitations of claims 2 and 3 further define the structure over what has already been claimed. Describing "wherein at least some part of said foot wrap overlaps at least some part of said wound dressing" is merely describing intended use. This is describing how the foot wrap is placed on the body relative to the wound dressing. This is dependent on how the device is used and doesn't appear to further define the structure. How is the structure of the foot wrap or wound dressing further limited by this language? Claim 4 also has similar language.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Thorn et al.
6. Jacobs teaches a foot wrap having an inflatable bladder for applying compressive force over the lower leg and foot of a patient. Jacobs also teaches that the foot wrap can be used in

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Page 3

Art Unit: 3764

combination with a wound dressing column 6, lines 4-7. Thorn teaches a conventional wound dressing for introducing negative pressure over any area of the patient. It would have been obvious to one of ordinary skill in the art to modify Jacobs to use the foot wrap in combination with a wound dressing as taught by Thorn in order to complete the teaching of Jacobs. The free and open arrangement of the Jacobs wrap allows free placement of the wound dressing anywhere desired or required.

7. **Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tumey et al. in view of Thorn and Jacobs et al.** Tumey teaches a foot wrap having an inflatable bladder for applying a compressive force to the patient's foot. Jacobs teaches the convention of using wound dressings in combination with inflatable foot wraps and Thorn exemplifies wound dressings that apply a negative pressure. It would have been obvious to one of ordinary skill in the art to modify Tumey to include a wound dressing with the wrap as taught by Jacobs to be able to additionally treat wounds and to use the specific type of wound dressing as taught by Thorn as an obvious example of wound dressings. Tumey additionally teaches the convention of pressure sensors 47 to control pressurization.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Khouri teaches the convention of using vacuum sensors.

ddd
27 September, 2000
(703) 308-3713
Fax: (703) 305-3590
danton.demille@uspto.gov

Danton DeMille
Primary Examiner
Art Unit 3764



UNITED STATES PATENT AND TRADEMARK OFFICE

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BY: COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	APP. DOCKET NO./TITLE
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.A.45

30159
ATTN: LEGAL-MANUFACTURING
KINETIC CONCEPTS, INC.
P.O. BOX 659508
SAN ANTONIO, TX 78265-9508

CONFIRMATION NO. 8678



Date Mailed: 08/16/2002

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/17/2002.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

RECEIVED
AUG 21 2002

Sheila A Green
SHEILA A GREEN
3700 (703) 306-0410

ATTORNEY/APPLICANT COPY



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC331.A

22775
WAYNE J COLTON INC
THE MILAM BUILDING SUITE 1032
115 EAST TRAVIS STREET
SAN ANTONIO, TX 78205

CONFIRMATION NO. 8678



OC000000008635518

Date Mailed: 08/15/2002

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/17/2002.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).



Sheila A Green
SHEILA A GREEN
3700 (703) 306-0410

NEW ATTORNEY/AGENT COPY

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)ATTY DOCKET NO.
1004.1035

SERIAL NO.

APPLICANT(S)
Richard C. VOGEL et al.FILING DATE
December 10, 1999

GROUP

C511 U.S. PTO
09/458280**U.S. PATENT DOCUMENTS**

AMINER	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>20</i>	3,026,874 ✓	03/1962	Stevens	128	260	
<i>21</i>	4,382,441 ✓	05/1983	Svedman	604	291	
<i>22</i>	4,614,179 ✓	09/1986	Gamder et al.	128	64	
<i>23</i>	4,969,880 ✓	11/1990	Zamierowskit	604	305	
<i>24</i>	5,149,331 ✓	09/1992	Ferdman et al.	604	290	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
<i>25</i>	WO 93/09727 ✓	05/1993	PCT	A61	00		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>26</i>		U.S. patent application Serial No. 08/517,901 filed 08/22/95.
<i>27</i>		Kinetic Concepts, Inc., The VAC - Assisting in Wound Healing, 1997.

AMINER

D. DeMille

DATE CONSIDERED

9-26-00

AMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) 1004.1035	Application Number
		Applicant(s) Richard C. VOGEL <i>et al.</i>	
		Filing Date December 10, 1999	Group Art Unit
EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
CS	U.S patent application Serial No. 08/039,574 filed 03/25/93.		
CS	Kinetic Concepts, Inc., The Plexipulse All in 1 System, date unknown.		
CS	Dillon, Richard S., Treatment of Resistant Venous Stasis Ulcers and Dermatitis with the End-Diastolic Pneumatic Compression Boot, Angiology, The Journal of Vascular Diseases, vol. 37, pp. 47-56, 1986.		
CS	Gaskell, P. <i>et al.</i> , The Effect of a Mechanical Venous Pump on the Circulation of the Feet in Presence of Arterial Obstruction, Surgery, Gynecology & Obstetrics, vol. 146, pp. 583-92, 1978.		
CS	Herrmann, Louis G. <i>et al.</i> , The Conservative Treatment of Arteriosclerotic Peripheral Vascular Disease, Annal Sugery, vVol. 100, pp. 750-60, 1934.		
CS	Landis, Eugene M. <i>et al.</i> , The Clinical Value of Alternate Suction and Pressure in the Treatment of Advanced Peripheral Vascular Disease, American Journal of Medical of the Sciences, vol. 189, pp. 305-25, 1935.		
CS	Landis, Eugene M. <i>et al.</i> , The Effects of Alternate Suction and Pressure on Blood Flow to the Lower Extremities, The Journal of Clinical Investigation, vol. XII, pp. 925-61, 1933.		
CS	Murray, James, Influence on the Body on Increased and Diminished Atmospheric Pressure, The Lancet, pp. 909-17, 1835.		
EXAMINER	DATE CONSIDERED		
D. D. Mille		9/24/00	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION
(Use several sheets if necessary)

Docket Number (Optional)
1004,1035

Application Number

Applicant(s)
Richard C. VOGEL et al.

Filing Date
December 10, 1999

Group Art Unit

EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CC

Parrot, James C.W., The Effect of a Mechanical Venous Pump on the Circulation in the Feet in the Presence of Arterial Obstruction, Master's Thesis, University of Manitoba, Department of Physiology, 1972.

Q

Rastgeldi, Selahaddin, Pressure Treatment of Peripheral Vascular Diseases and Intermittent Pressure Treatment of Peripheral Vascular Diseases, pp. 1-49, 1972.

EXAMINER

DATE CONSIDERED

D. DeMille

9/24/00

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Notice of References Cited				Application/Control No		Applicant(s)/Patent Under Reexamination			
				09/458,280		Vogel et al.			
				Examiner		Art Unit			
				Danton DeMille		3764			
U.S. PATENT DOCUMENTS									
*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	DOCUMENT SOURCE **		
							APS	OTHER	
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<input type="checkbox"/>	B	5701917	Oct. 1997	Khourl	--	--	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	C	5443440	Aug. 1995	Tumey et al.	--	--	<input type="checkbox"/>	<input type="checkbox"/>	
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FOREIGN PATENT DOCUMENTS									
*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	DOCUMENT SOURCE **	
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<input type="checkbox"/>	N	2195255	Apr. 1988	GB	Thom et al.	601	6	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	O	201229	Oct. 1958	Austria	Muller et al.	601	6	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	P	638309	May. 1928	France	Bernd	601	6	<input type="checkbox"/>	<input type="checkbox"/>
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NON-PATENT DOCUMENTS									
*		DOCUMENT (Including Author, Title Date, Source, and Pertinent Pages)						DOCUMENT SOURCE **	
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<input type="checkbox"/>	X							<input type="checkbox"/>	<input type="checkbox"/>

*A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)

**APS encompasses any electronic search i.e. text, image, and Commercial Databases.

U.S. Patent and Trademark Office

PAGE 10/93 * RCVD AT 9/20/2006 1:00:12 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/22 * DNIS:2738300 * CSID:210 255 6969 * DURATION (mm-ss):32-14

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601-6

KCI Concepts Inc.
AU 3702 45812
AT 000201229 B
DEC 1958

No. 3627 P. 11

Österreichisches Patentamt
Patentschrift

Nr. 201229

Kl. 30 c, 8/20

1 Blatt

EXAMINER'S

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D.V. 55

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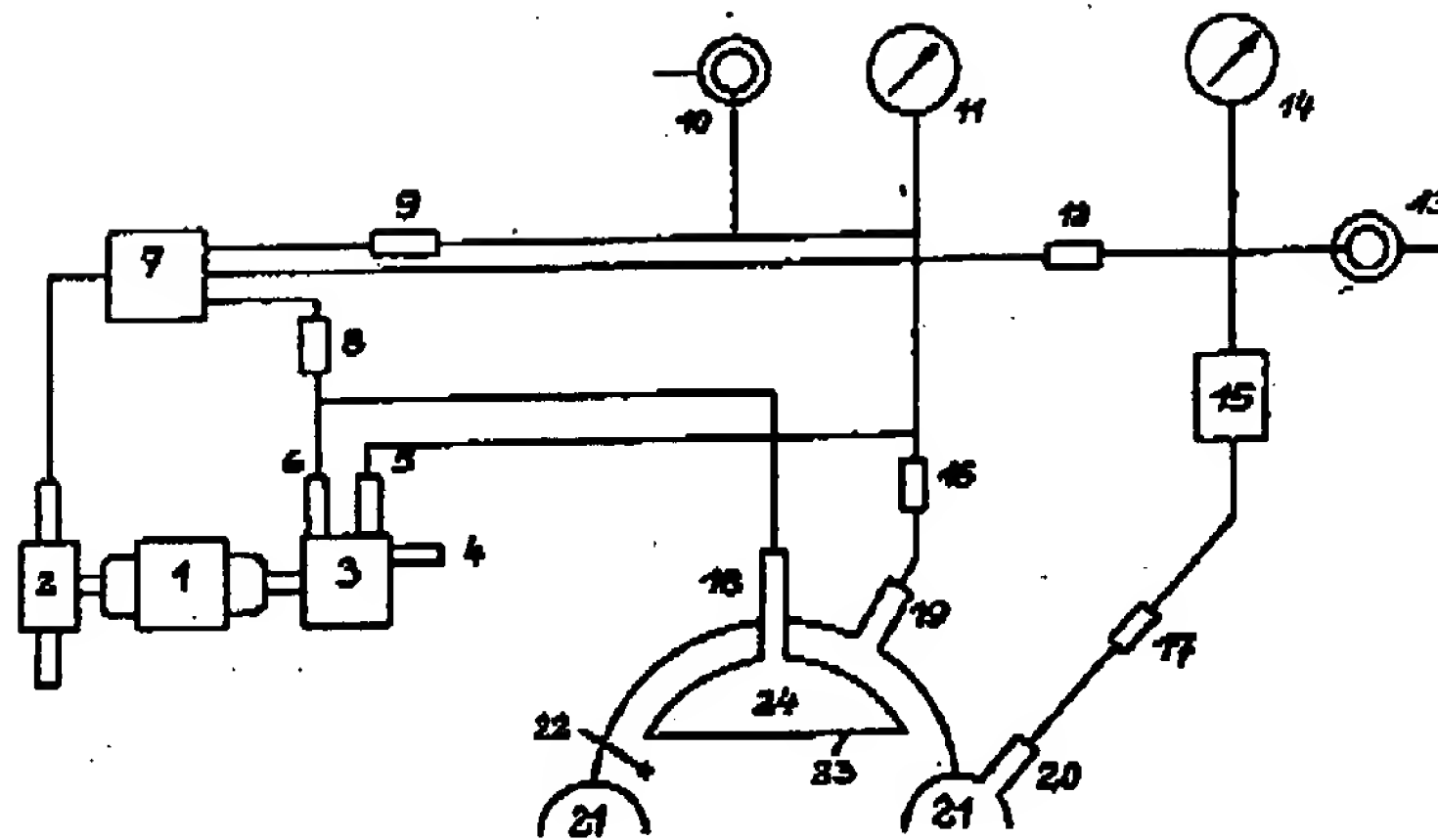


Fig. 1

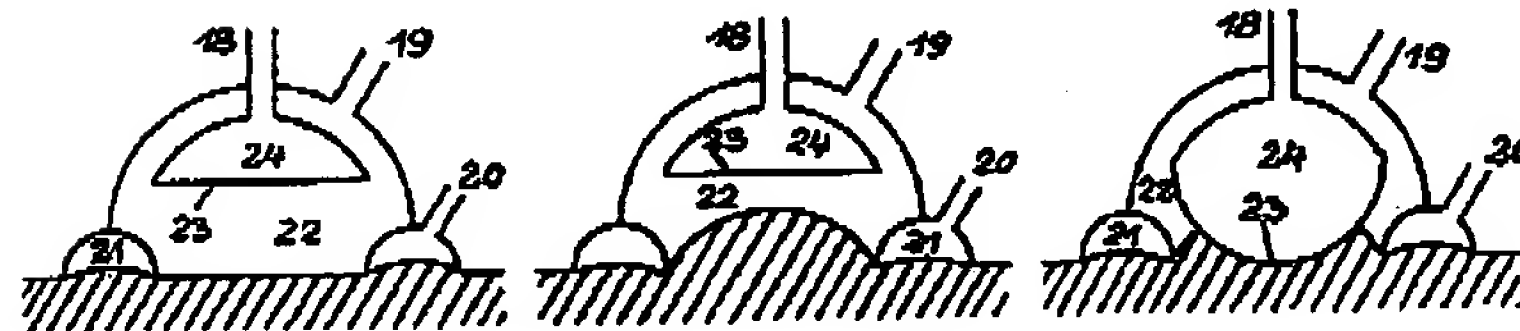


Fig. 2

Fig. 3

Fig. 4

601/6



ÖSTERREICHISCHES PATENTAMT

Kl. 30 c, 8/20

PATENTSCHRIFT NR. 201229

Ausgegeben am 10. Dezember 1958

OSKAR MÜLLER UND DR. HANS LACKNER IN WIEN

Saug- und Druckmassage-Apparat

Angemeldet am 14. Juni 1957. — Beginn der Patendauer: 15. Juni 1958.

Der Gegenstand der Erfindung bezieht sich auf einen Saug- und Druckmassage-Apparat. Es sind bereits Apparate bekannt, die im Außenbecher angeordnete Massagevorrichtungen be-
nützen. Die deutsche Patentschrift Nr. 532086 (Stephani) benützt einen Anschlag für die Haut oder einen Vibrationsmassage-Apparat im Saugbecher. Zur Erzeugung des Vakuums wird ein Staubsauger verwendet, dessen Vakuum durch
zwei verstellbare Löcher groß regelbar ist.

In den beiden, einander ähnlichen, britischen Patenten Nr. 14.989 A. D. 1914 (Winton-Charteris) und Nr. 369.165 (Hinder) ist ein aus Gummi oder anderem flexiblem Material hergestellter Becher an einem Stiel befestigt, der im Außenbecher gleitend angeordnet ist. Der Außenbecher wird mit der einen Hand auf die Haut gedrückt, welche dadurch gespannt wird, die zweite Hand bearbeitet mit dem
Innenbecher, das durch den Außenbecher gehaltene Stückchen Haut, wobei Saug- und Druckwirkungen zustande kommen.

Der Vorteil, den der Erfindungsgegenstand gegenüber den angeführten Patenten bietet, besteht darin, daß er die Wirkung einer Saugmassage und die nachfolgend zu ersetzende Handmassage in einem Arbeitsgang und mittels einer automatisch arbeitenden Vorrichtung vereint.

Fig. 1 zeigt die schematische Schaltung eines Massagegerätes. Ein Elektromotor 1 treibt eine Vakuumpumpe 2, welche einen Windkessel 7 evakuiert. Über eine Düse 9 mit zirka 0,4 mm² und ein Filter 16 wird der Raum 22 durch den Schlauchanschluß 19 am Saugbecher evakuiert. Das Vakuum in dieser Leitung ist durch das Reduzierventil 10 regelbar und das Vakuummeter 11 kontrollierbar. Die gleiche Leitung kann über die Steuereinrichtung 3 und deren Anschluß 5 über die durchbohrte Achse 4 mit der Außenluft in Verbindung gebracht und damit eine Vakuumverminderung im Raum 22 herbeigeführt werden (Fig. 2).

Aus dem Windkessel 7 führt eine zweite Leitung über eine Düse 12 von 0,1 mm² in einen zweiten Windkessel 13, dessen Vakuum durch das Reduzierventil 14 regelbar und das Vakuummeter 15 meßbar ist. Der Windkessel 13 ist über

das Filter 17 und den Schlauchanschluß 20 mit dem Saugrand 21 des Massagebechers in Verbindung.

Eine dritte Leitung aus dem Windkessel 7 führt über die Düse 8 mit einem Durchmesser von 0,1 mm² in den Druckbecher 24. Diese Leitung ist über den Anschluß 6 der Steuereinrichtung und deren durchbohrte Achse 4 mit dem normalen Luftdruck verbunden.

Die Massagevorrichtung selbst besteht schematisch (Fig. 1) aus einem Außenbecher mit dem Saugraum 22 und einem Schlauchanschluß 19. Der Rand des Bechers ist als Hohlrand 21 ausgebildet mit einem Schlauchanschluß 20. Im Außenbecher ist ein Innenbecher 24 befestigt, dessen hautseitige Öffnung mit einer Membrane 23 luftdicht verschlossen ist.

Zur Funktion des Gerätes wird der Massagebecher, wie in Fig. 2 gezeigt, auf die Haut aufgesetzt. Der Hohlrand 21 saugt sich fest. Dann wird auch der größere Raum 22 evakuiert und die Haut wird, wie in Fig. 3, in den Raum 22 hineingezogen. Nun wird durch die Steuervorrichtung 3 der Raum 24 mit der Außenluft verbunden. Dadurch lastet auf der Membrane 23 ein Gasdruck, der gleich der Differenz ist, zwischen dem am Vakuummeter 11 abzulesenden Vakuum und dem am Behandlungsort herrschenden Luftdruck, weniger der Retraktionskraft der Membrane. Aus diesem Grund muß die Membrane aus dünnem, hochelastischem Material sein. Sie wird, wie in Fig. 4 gezeigt, durch die Druckdifferenz gegen die Haut gedrückt. Zur regelmäßigen Wiederholung dieser Saug- und Druckvorgänge dient die Steuervorrichtung 3.

PATENTANSPRÜCHE:

1. Saug- und Druckmassage-Apparat mit einem im Innern des Saugbechers (22) angeordneten Druckbecher (24), dadurch gekennzeichnet, daß die hautseitige Öffnung des Druckbechers durch eine luftdicht schließende, elastische Membrane (23) abgeschlossen ist.

2. Massageapparat nach Anspruch 1, dadurch gekennzeichnet, daß der Rand des Saugbechers als Hohlrand (21) ausgebildet ist, der beim Auf-

(12) UK Patent Application (19) GB (11) 2 195 255 (13) A

(43) Application published 7 Apr 1988

(21) Application No 8623412

(22) Date of filing 30 Sep 1986

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(51) INT CL⁴
A61H 7/00 9/00

(52) Domestic classification (Edition J):
A5R EQ

(56) Documents cited
GB A 2149855 GB 1110824 GB 0379824

(58) Field of search
A5R
Selected US specifications from IPC sub-class A61H

(54) Method and apparatus for vacuum treatment of an epidermal surface

(57) When treating an epidermal surface (surface of the skin) (3) with subatmospheric pressure supplied from a source (not shown) through a flexible tube (6), an applicator (4) is used consisting of a first, porous layer (7) of e.g. felt and a second, airtight layer (8) of e.g. plastic sheet material, the edge portions (9) of which extend beyond the first layer (7) and form a seal against the epidermal surface (3).

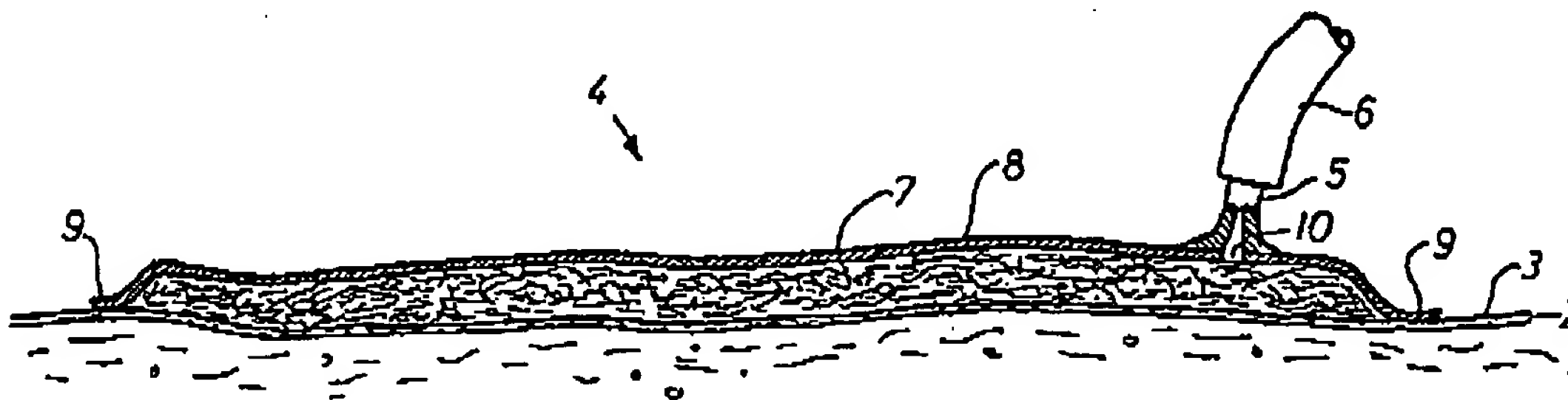


Fig.1

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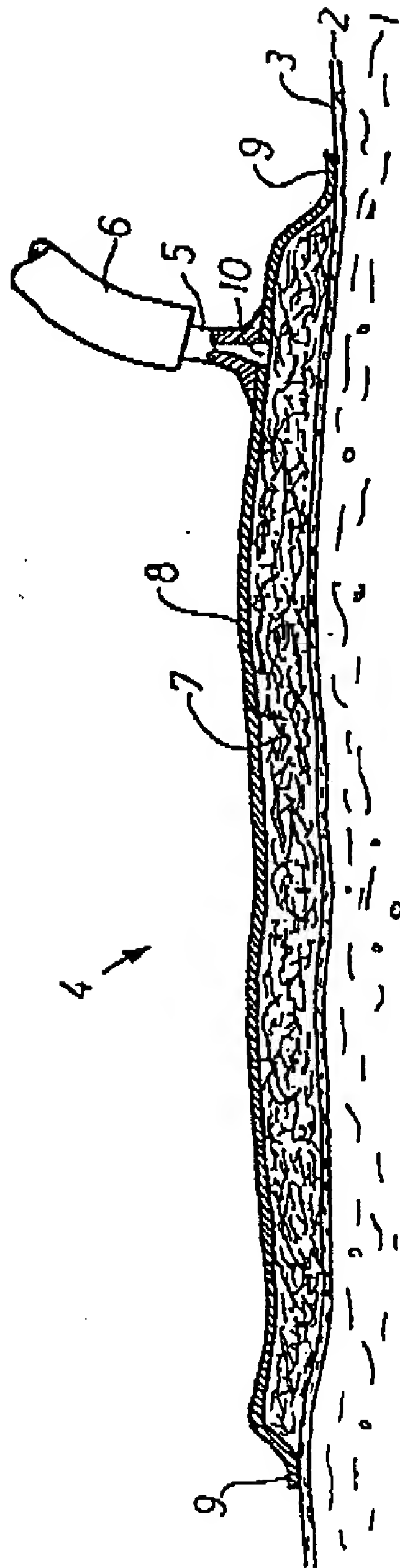


Fig. 1

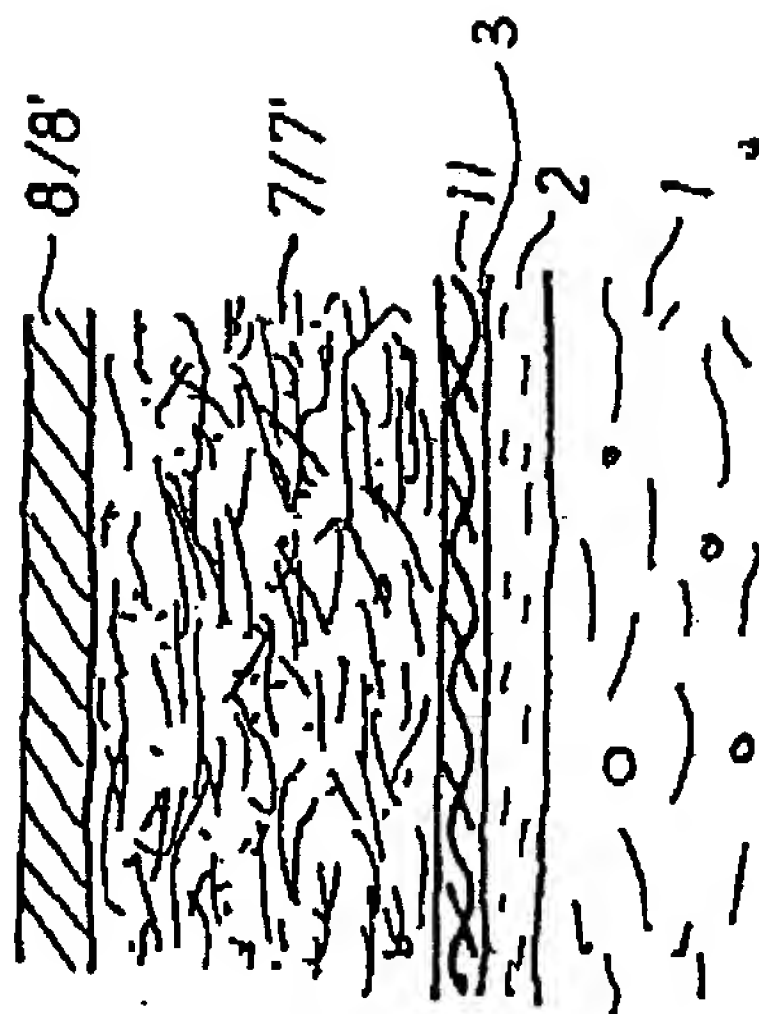


Fig. 3

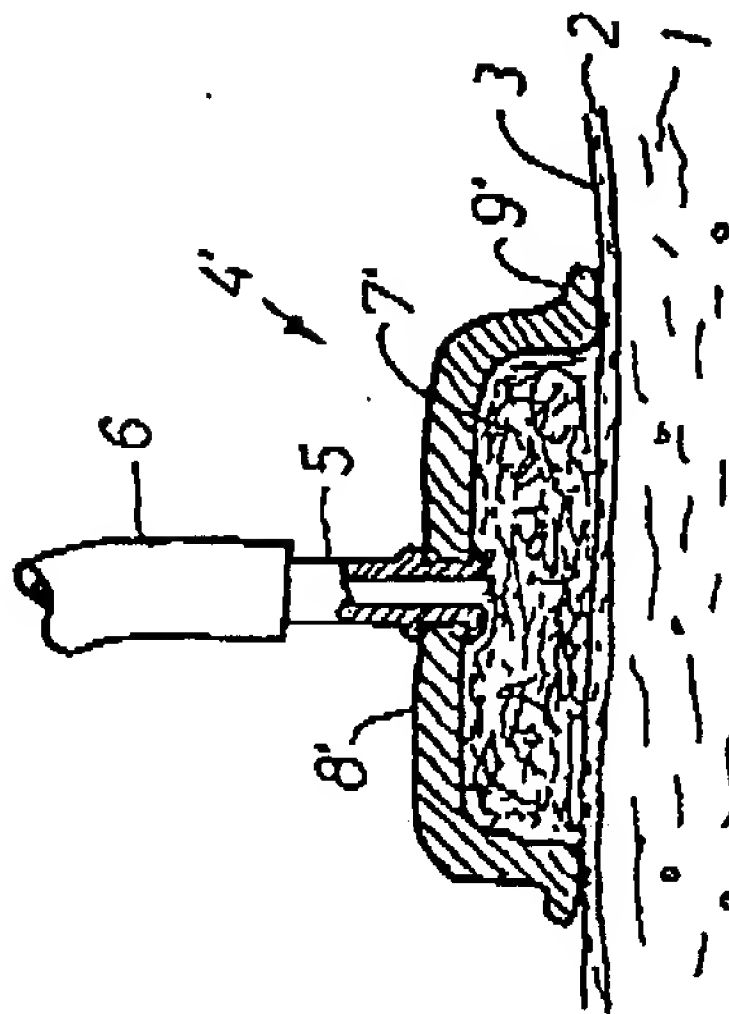


Fig. 2

SPECIFICATION

Method and apparatus for vacuum treatment of an epidermal surface

- 5 The present invention relates to a method of applying subatmospheric pressure or partial vacuum to an epidermal surface.
- 10 Previously known methods of this kind usually involve placing the limb or other part of the body whose epidermal surface is to be treated with subatmospheric pressure, in a closed airtight chamber which is then evacuated, for example, by using a vacuum pump.
- 15 To prevent the walls of the chamber from collapsing under the influence of atmospheric pressure, they must have considerable strength, especially in consideration of the subatmospheric pressure possibly being as low
- 20 as 0.55 bar, corresponding to an external positive pressure on the chamber of almost half an atmosphere. Since the limb or part of the body in question is necessarily connected at one end to the body of the person in question, special measures must be taken to form an air-tight seal between that end of the vacuum chamber, through which the part of the body has been introduced, and that part itself.
- 25 In cases where the subatmospheric pressure is to be applied to a large part of the body of the person in question, such as the part comprising the thorax and the abdominal cavity, the application of subatmospheric pressure to the outside of this part of the body may
- 30 cause internal organs containing air or gases to be distended, and breathing may be disturbed.
- Another disadvantage with the known methods is that the space within the vacuum chambers around the part of the body or limb
- 40 may need to be of rather large volume, for which reason it may take a long time to evacuate them.
- It is an object of the present invention to
- 45 provide a method of the kind referred to free of the disadvantages mentioned above and being suitable for implementation by personnel without great technical ability with regard to operating apparatus.
- 50 According to the present invention there is provided a method of applying subatmospheric pressure to an epidermal surface, said method being of the kind comprising the formation of an airtight space outside said surface, said
- 55 space being connected to a source of subatmospheric pressure activated to lower the pressure in said space, characterised in that said airtight space is formed by
- (a) placing on and/or along said epidermal
- 60 surface a first layer consisting of a porous and preferably flexible material of a kind comprising mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

and preferably also on the part of the epidermal surface closest thereto and not covered by said first layer, a second layer consisting of airtight and preferably flexible material.

- 70 Such a method is extremely easy to carry out, and provides partly the advantage that the force on the epidermal surface caused by the subatmospheric pressure is counterbalanced by the mechanical force produced by the same subatmospheric pressure acting on the second layer and hence on the epidermal surface. This force does, however, act on the epidermal surface solely on the relatively limited contact areas between the pores in the
- 80 first layer, so that the epidermal surface facing the pores is fully influenced by the subatmospheric pressure. Experience has shown that the effect on the cutis and possibly underlying tissue is not inferior to the effect obtainable
- 85 by using the previously known methods mentioned above.

The present invention also relates to an applicator for use in carrying out the method of the invention.

- 90 The invention will be further apparent from the following description with reference to the accompanying drawing in which:

Figure 1 is a sectional view showing a region of skin with an applicator according to a first embodiment placed thereon;

95 Figure 2 is a sectional view similar to Figure 1 through a skin region with an applicator according to a second embodiment; and

Figure 3 shows the use of a protective layer

100 between the skin and the applicator on an enlarged scale.

The drawings show diagrammatically a skin region consisting of subcutis 1 and epidermis 2, the latter having an external epidermal surface 3.

105 With the purpose of applying subatmospheric pressure to a part of the epidermal surface 3, there is on that surface placed a vacuum applicator 4, being connected to a source (not shown) of reduced pressure, which may be of a previously known type, through a tube-connecting stub 5 and a flexible tube 6.

115 In the embodiment shown in Figure 1, the vacuum applicator comprises a first layer 7, lying in contact with a part of the epidermal surface 3. The first layer 7 consists of porous material, the pores of which are interconnected and do not close upon application of a compressive force to the material. Such a material may for example be felt, which—as is well known—consists of mutually entangled fibres of wool or other natural or synthetic fibre. The vacuum applicator 4 further comprises a second layer 8, placed on top of

120 (outside of) the first layer 7 and being so much larger than the latter in the extent of its area, that it is also in direct contact with the epidermal surface 3 with an edge portion 9

example, be constituted by a thin sheet of plastics or rubber. To make it possible to adapt the shape of the vacuum applicator 4 to the shape of the limb or body part in question, both the first layer 7 and the second layer 8 should be flexible, and this condition is fulfilled by using the materials mentioned.

In the second layer 8 there is formed a hole 10, and the tube-connecting stub 5 is secured to the second layer 8 in such a manner, such as by means of glue or cement, that the opening in the stub 5 communicates with the hole 10.

When the source (not shown) of subatmospheric pressure is connected to the flexible tube 6 the space between the epidermal surface 3 and the inside of the second layer 8 is evacuated through the stub 5 and the hole 10. If the first layer 7 were not present in this space, then the space would collapse immediately at the onset of the evacuation, and the second layer 8 would contact the epidermal surface in a fluid-tight manner, so that the subatmospheric pressure in the flexible tube 6 would be unable to reach the region of the epidermal surface covered by the vacuum applicator 4. The porous first layer 7 does, however, in a purely mechanical manner keep the second layer 8 spaced from the epidermal surface 3, for which reason the subatmospheric pressure between the fibres in the first layer 7 can propagate through the entire space between the epidermal surface 3 and the second layer 8, so that the part of the epidermal surface underlying the first layer 7 will in its entirety be subjected to subatmospheric pressure. At the same time, the epidermal surface 3 will be subjected to a mechanical force acting thereupon from the most adjacent fibres in the first layer 7, but since these fibers will only be in contact with a limited portion of the area of the epidermal surface 3, the major part of this surface will be subjected to the subatmospheric pressure.

Apart from the weight of the vacuum applicator 4, no net mechanical force is applied to the limb or body part comprising the epidermal surface 3, because the surface 3 is partly acted upon by an upwardly directed force corresponding to the magnitude of the subatmospheric pressure multiplied by the area in question, while the epidermal surface 3 at the same time is acted upon by a downwardly directed force transmitted through the first layer 7, said downwardly directed force being caused by the effect of the very same subatmospheric pressure acting on the inside of the second layer 8, the area of which is substantially the same as the area of the epidermal surface 3 being acted upon. In spite of the apparently paradoxical situation involving the epidermal surface 3 simultaneously being acted upon by two equal and oppositely directed forces, the subatmospheric pressure

below or behind the epidermal surface 3, since the subatmospheric pressure has access to the tissue through a rather large percentage of the surface, only the remaining part of the surface being acted upon by the mechanical force as directed downwards in Figure 1.

Thus, practice has shown that by using a vacuum applicator constructed according to the principles illustrated in Figure 1 and explained in the foregoing, it is possible to obtain an effect on the cutis 1 2 and possibly the underlying tissue at least as effective as that obtainable using previously known apparatus for subjecting epidermal surfaces to subatmospheric pressures.

The first and second layers 7 and 8 respectively shown in Figure 1 may be extended in all directions and shaped in such a manner, that they for example form a bag-like or sleeve-like structure, that may be placed around a greater or smaller part of the body in question. In certain instances, however, it may be desirable to apply subatmospheric pressure to a very limited region of the epidermal surface, and in such cases it is possible to employ a vacuum applicator 4' as shown diagrammatically in Figure 2. Like the vacuum applicator 4 shown in Figure 1, the vacuum applicator 4' shown in Figure 2 also consists of a first layer 7' and a second layer 8'. Of these, the first layer 7' may—apart from the size—be identical to the first layer 7 shown in Figure 1, while the second layer 8' as shown in Figure 2 may be constituted by a vacuum cup, with which the tube-connecting stub 5 and with it the flexible tube 6 are connected in a known manner. The edge portion 9' of the vacuum cup 8' provides the requisite sealing effect against the epidermal surface 3.

In order to avoid the first layer 7 or 7' becoming dirty and to prevent the transmission of infectious matter from one person to another, it is possible as shown in Figure 3 to place a protective layer 11 between the epidermal surface 3 and the first layer 7 or 7'. The protective layer 11 should—of course—be made of a material capable of both transmitting the subatmospheric pressure and the mechanical force from the first layer 7 or 7', and to this end the protective layer 11 can suitably consist of a textile material, such as sheeting or the like, that may be disposable or laundered and/or sterilized.

The subatmospheric pressure being transmitted to the epidermal surface 3 by means of the vacuum applicator 4 or 4' may be of the order of magnitude 0.05 to 0.55 bar. The source of subatmospheric pressure (not shown) connected to the flexible tube 6 may be provided with means to adjust the subatmospheric pressure, possibly also means to vary this pressure in a preprogrammed manner, so that the subatmospheric pressure

ing the desired effect on the epidermal region in question, possibly also the underlying tissue.

It will be appreciated that it is not intended to limit the invention to the above example only, many variations, such as might readily occur to one skilled in the art, being possible, without departing from the scope thereof as defined by the appended claims.

10

CLAIMS

1. a method of applying subatmospheric pressure to an epidermal surface, said method being of the kind comprising the formation of an airtight space outside said surface, said space being connected to a source of subatmospheric pressure activated to lower the pressure in said space, characterised in that said airtight space is formed by

(a) placing on and/or along said epidermal surface a first layer consisting of a porous and preferably flexible material of a kind comprising mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

(b) placing on the outside of said first layer and preferably also on the part of the epidermal surface closest thereto and not covered by said first layer, a second layer consisting of airtight and preferably flexible material.

2. A method according to claim 1, characterised by using as the first layer a layer of fibrous material.

3. A method according to claim 1 and claim 2 wherein said first layer is of felt.

4. A method according to claim 1, 2 or 3 characterised by using as the second layer a flexible sheet or foil.

5. A method according to claim 1 and claim 4 wherein said second layer is of plastics.

6. A method according to claim 1, 2 or 3 characterised by using as the second layer a vacuum cup, the internal space of which has substantially the same height as said first layer, and the peripheral edge of which is in contact with the epidermal surface around the first layer.

7. A method according to any one or any of the claims 1-6, characterised in that a protective layer of air-permeable material is placed on the epidermal surface prior to the first layer being placed thereon.

8. A method according to claim 7 wherein said protective layer is a textile material.

9. An applicator for carrying out the method according to any one or any of the claims 1-8, characterised by

(a) a first layer consisting of porous and preferably flexible material of the kind with mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

(b) a second layer adapted to be placed on the outside of the first layer and consisting of airtight and preferably flexible material, said

second layer having a greater extent in area than said first layer and comprising means for connecting the space below or behind said second layer with a source of subatmospheric pressure.

10. An applicator according to claim 9, characterised in that said first layer consists of fibrous material.

11. An applicator according to claim 10 wherein said first layer is of felt.

12. An applicator according to claim 9, 10 or 11 characterised in that said second layer consists of flexible sheet material

13. An applicator according to claim 12 wherein said second layer is of plastics.

14. An applicator according to claim 9, 10 or 11 characterised in that said second layer consists of a vacuum cup, the internal space of which has substantially the same height as the first layer and the peripheral edge of which is adapted to be in contact with the epidermal surface around said first layer.

15. An applicator according to any one or any of the claims 9-14 characterised by a protective layer of air permeable material adapted to be placed between the epidermal surface and the first layer.

16. An applicator according to claim 15 wherein said protective layer is a textile material.

Published 1888 at The Patent Office, State House, 68/71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office, Sales Branch, St Mary Cray, Orpington, Kent BR5 3RD. Printed by Burgess & Son (Abingdon) Ltd. Con 1/97

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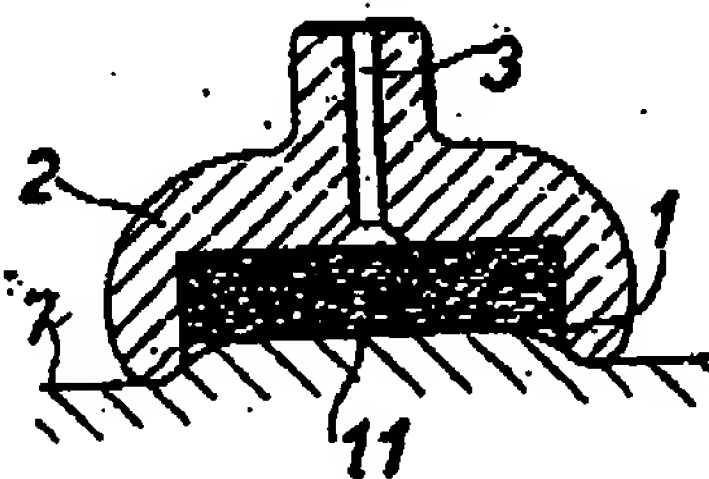
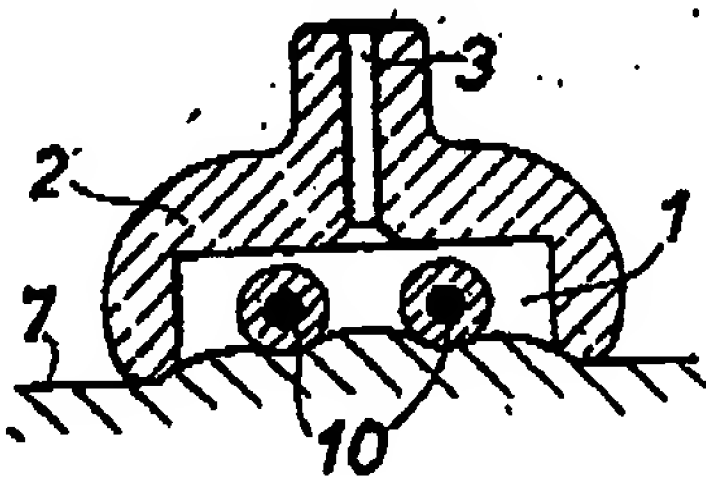
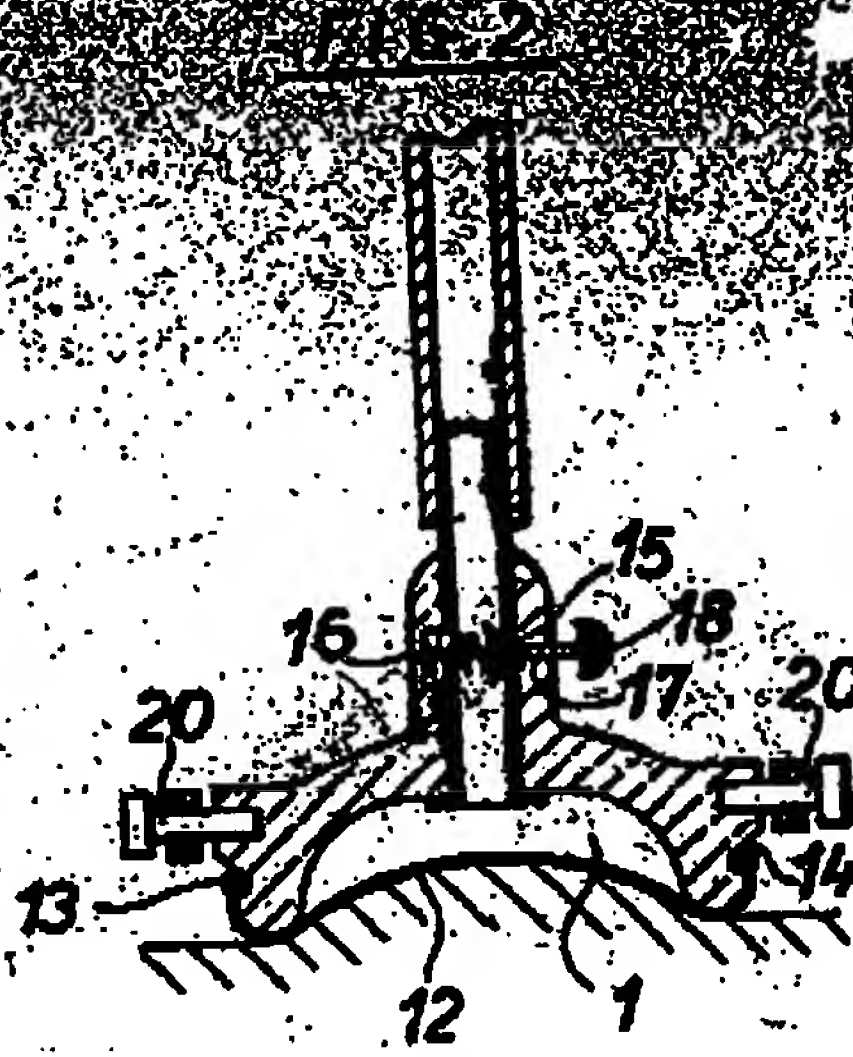
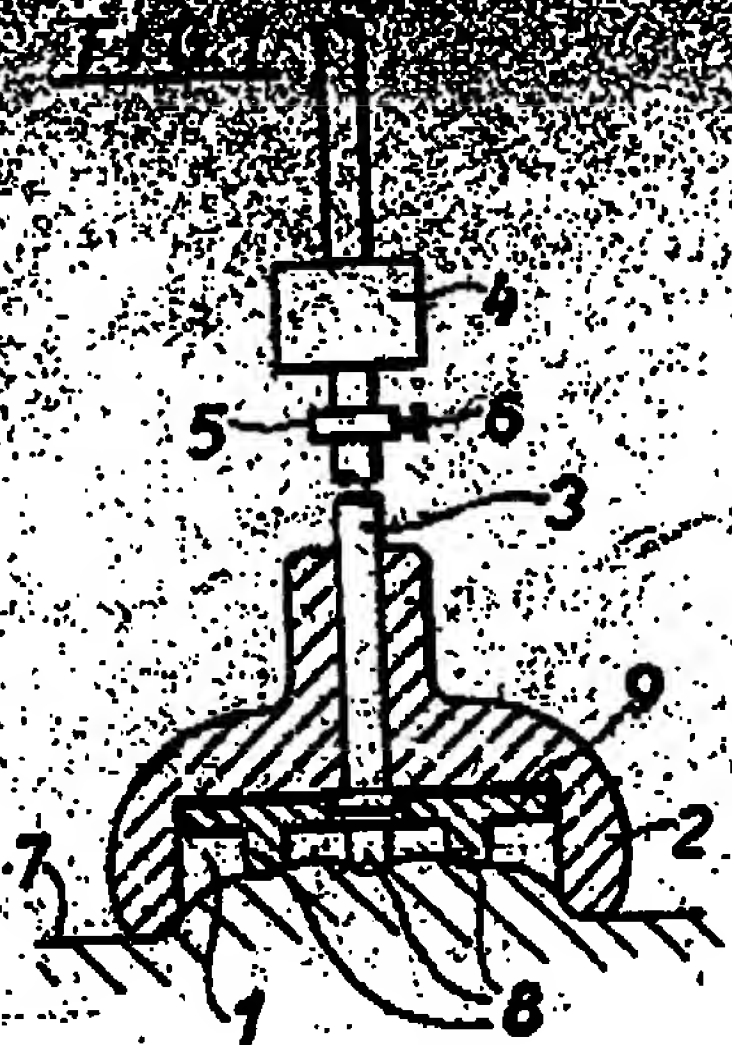
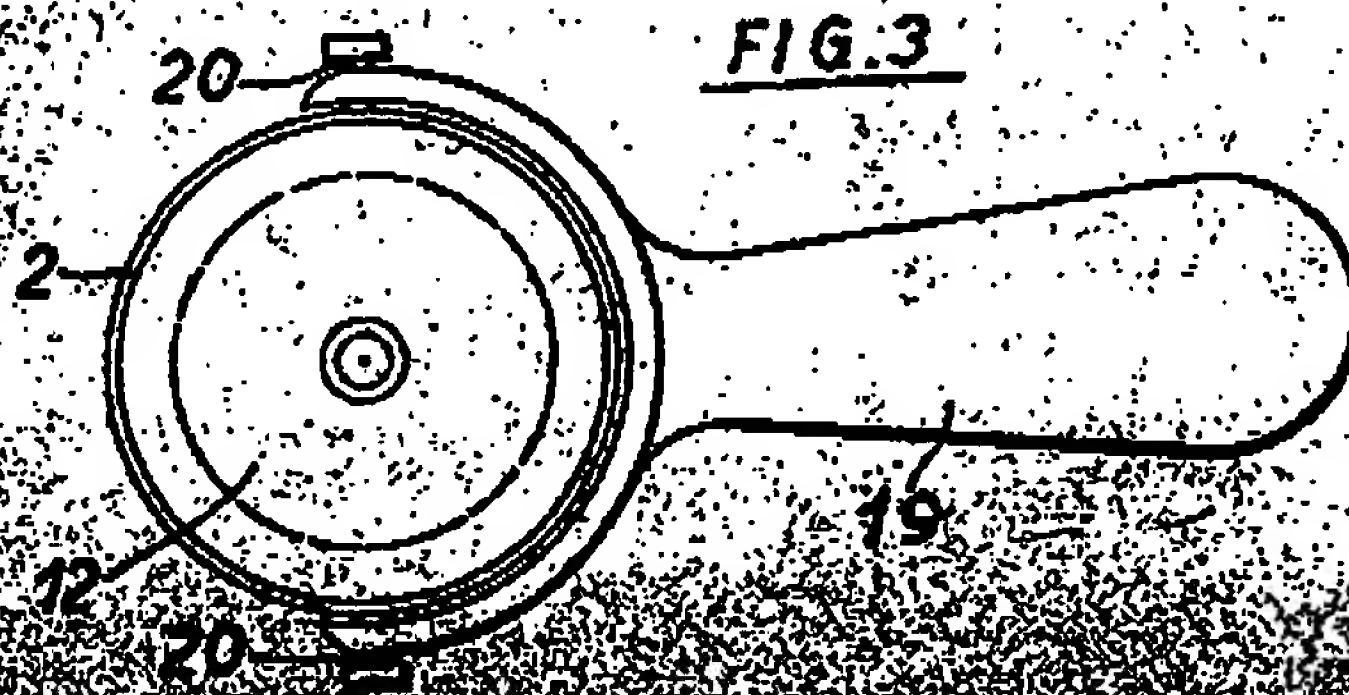
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3 figs. spec



Prusse mass

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— 2 —

Les figures 2 et 3 montrent, respectivement, en élévation, avec coupe partielle, et en plan, une autre forme d'exécution du bol d'aspiration et de sa liaison avec la poignée.

Les figures 4 et 5 montrent, en coupe médiane verticale, deux autres formes d'exécution du bol d'aspiration.

Ainsi que le montre la forme d'exécution d'après la figure 1, l'organe de massage 2, constitué comme un bol d'aspiration, et comprenant la chambre creuse 1 en forme de cloche, est relié, au moyen de la canalisation d'aspiration 3, à une pompe d'aspiration 4 d'un type quelconque. Une soupape de réduction 5 est disposée entre la pompe et l'organe de massage, la vis 6 permettant de régler cette soupape au degré de dépression voulu. La soupape de réduction peut aussi être fixée sur l'organe de massage lui-même, ou sur la pompe. De même, en supprimant la canalisation de liaison, la pompe peut être réunie avec l'organe de massage.

Si la pompe 4 est mise en action, et que la soupape de réduction 5 soit convenablement réglée, une dépression permanente est produite dans la chambre creuse 1 de l'organe de massage 2, de telle sorte que, ainsi que le montre la figure 1, la surface de la peau 7 de la partie du corps qui subit le massage 30 pénètre quelque peu à l'intérieur de la chambre creuse. Si, alors, l'organe de massage est déplacé à la main sur le corps, la pompe d'aspiration 4, qui travaille continuellement, maintient constamment la dépression 35 au degré voulu.

Afin d'éviter une pénétration trop forte de la peau à l'intérieur du bol, on peut, conformément à l'invention, disposer, à l'intérieur du bol d'aspiration 2, des dispositifs 40 qui permettent de soutenir la peau. D'après la figure 1, on a prévu, dans ce but, plusieurs saillies 8 qui peuvent être disposées sur une plaque 9, laquelle peut être placée dans le bol d'aspiration 2. On peut aussi utiliser 45 des galets 10, qui peuvent tourner sur leurs axes (fig. 4) et qui agissent également pour renforcer l'action de massage; on peut aussi employer une masse poreuse 11 (fig. 5), par exemple en caoutchouc. D'ailleurs, dans le même but, on peut disposer, dans la surface 50 d'aspiration, des trous, ou bien des barreaux transversaux qui servent de supports. La

surface d'aspiration peut aussi être établie en forme de grille, et il est clair que le support de la peau peut aussi être obtenu par 55 tous autres dispositifs de supports appropriés. L'organe de massage peut aussi être constitué sous forme de plusieurs bols d'aspiration, fixés les uns aux autres de toute manière appropriée. 60

Les figures 2 et 3 montrent une autre forme d'exécution dans laquelle la chambre creuse de l'organe de massage 2 est recouverte par une membrane 12 se composant d'une matière flexible, cette membrane étant 65 maintenue à l'état de tension par un jonc d'arrêt 13 pénétrant dans une gorge 14 de l'organe de massage. Le recouvrement constitué par la membrane 12 a pour objet d'empêcher que des onguents, crèmes, 70 pomades, etc., qui peuvent être employés en vue du massage, ne puisse parvenir dans la canalisation d'aspiration. Lorsque, sous l'action de l'aspiration, la membrane 12 a complètement pénétré dans la chambre 1, et 75 recouvre par conséquent le débouché de la canalisation d'aspiration 3, que cette membrane obture, la dite membrane doit être ramenée dans sa position initiale. A cet effet, on utilise un organe de fermeture, par exemple une soupape conique 15, laquelle est 80 pressée sur son siège par le ressort 16; le siège de la soupape 15 termine un conduit 17 qui relie la canalisation d'aspiration avec l'air extérieur. Par le bouton 18, la 85 soupape 15 peut être ouverte, de telle sorte que l'action d'aspiration est interrompue, et que la membrane 12 est ramenée dans la position initiale. La disposition de l'organe de fermeture 15 et du canal 17 débouchant 90 à l'extérieur peut aussi être employée dans des appareils de massage sans membrane, et, dans ce cas, sert à équilibrer la différence de pressions par liaison avec l'air extérieur, de manière à interrompre immédiatement l'action 95 de massage. La soupape de réduction 6 peut ne former qu'un seul et même organe avec le système de fermeture 15.

Dans la forme d'exécution représentée par les figures 2 et 3, le bol d'aspiration de 100 l'organe de massage 2 est entouré par une poignée 19 établie en forme d'étrier, cette poignée pouvant tourner sur des axes 20, de telle sorte que, sans que la canalisation

5° Le dispositif d'aspiration en surpression agissant continuellement, est disposé sur l'organe de massage avec interruption d'une canalisation d'aspiration de compression telle qu'un tube de compression.

6° Le dispositif d'aspiration ou de surpression agissant continuellement, est réglable suivant les besoins, par un système de réduction réglable.

7° On dispose un organe de massage dans la canalisation qui relie l'organe de massage avec le dispositif d'aspiration de compression agissant en permanence. L'ouverture de ce dispositif aspirant, par la brèche de la différence de pression, la liaison avec la canalisation d'aspiration ou de surpression pouvant, en même temps, être fermée.

8° Le système de réduction est constitué par un système de réduction de pression.

5° Le dispositif d'aspiration en surpression agissant continuellement, est disposé sur l'organe de massage avec interruption d'une canalisation d'aspiration de compression telle qu'un tube de compression.

6° Le dispositif d'aspiration ou de surpression agissant continuellement, est réglable suivant les besoins, par un système de réduction réglable.

7° On dispose un organe de massage dans la canalisation qui relie l'organe de massage avec le dispositif d'aspiration de compression agissant en permanence. L'ouverture de ce dispositif aspirant, par la brèche de la différence de pression, la liaison avec la canalisation d'aspiration ou de surpression pouvant, en même temps, être fermée.

8° Le système de réduction est constitué par un système de réduction de pression.

9° Le système de réduction est constitué par un système de réduction de pression.

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19° Le système de réduction est constitué par un système de réduction de pression.

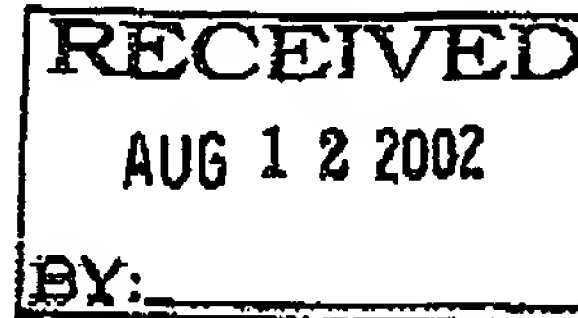
20° Le système de réduction est constitué par un système de réduction de pression.

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Paper No. 10

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ON PETITION

In re Application of
Richard Vogel
Application No. 09/458,280
Filed: December 10, 1999
Attorney Docket No. VAC.331.1

This is a decision on the petition under 37 CFR 1.137(b), filed June 17, 2002, to revive the above-identified application.

The petition is **GRANTED**.

The above-identified application became abandoned for failure to respond in a timely manner to the non-final Office action mailed October 4, 2000, which set a shortened statutory period of three months. Accordingly, the application became abandoned on January 5, 2001.

The application file is being forwarded to Technology Center AU 3764 for further processing.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-6911.

Latrice Bond
Paralegal Specialist
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

DOCKET DATE: 2-6-03
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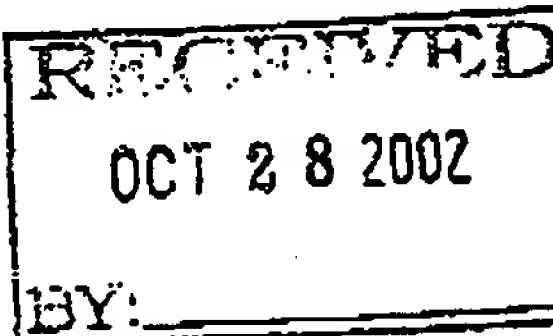
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.A	8678

30159 7590 10/21/2002

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VAC.331A.US

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Office Action Summary

Application No.

09/458,280

Applicant(s)

VOGEL ET AL.

Examiner

Danton DeMille

Art Unit

3764

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s) _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Application/Control Number: 09/458,280
Art Unit: 3764

Page 2

DETAILED ACTION***Claim Rejections - 35 USC § 103***

1. **Claims 1-5, 10-13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Thorn et al.**
2. Jacobs teaches a foot wrap having an inflatable bladder for applying compressive force over the lower leg and foot of a patient. Jacobs also teaches that the foot wrap can be used in combination with a wound dressing column 6, lines 4-7. Clearly the inflatable bladder of Jacobs is capable of overlapping at least a portion of the wound dressing since it is taught that the releasable securing means allows the patient to take the device off to access the wound dressing. Thorn teaches a conventional wound dressing for introducing negative pressure over any area of the patient. It would have been obvious to one of ordinary skill in the art to modify Jacobs to use the foot wrap in combination with a wound dressing as taught by Thorn in order to complete the teaching of Jacobs. The free and open arrangement of the Jacobs wrap allows free placement of the wound dressing anywhere desired or required. Regarding claim 13, Thorn teaches a layer 7 of porous material. The porous material can be of any well known design as long as it maintains the space between the skin and the second layer 8. Open celled elastic foam is just such a conventional material and an obvious provision.
3. **Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tumey et al. in view of Thorn and Jacobs et al.** Tumey teaches a foot wrap having an inflatable bladder for applying a compressive force to the patient's foot. Jacobs teaches the convention of using wound dressings in combination with inflatable foot wraps and Thorn exemplifies wound dressings that apply a negative pressure. It would have been obvious to one of ordinary skill in

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the art to modify Turney to include a wound dressing with the wrap as taught by Jacobs to be able to additionally treat wounds and to use the specific type of wound dressing as taught by Thorn as an obvious example of wound dressings. Turney additionally teaches the convention of pressure sensors 47 to control pressurization. Turney teaches the pressure source is intermittently operable. Thorn teaches the vacuum source can be operable to vary the negative pressure in a preprogrammed manner to provide the desired effect. The art teaches intermittent pressure application therefore providing intermittent negative pressure would have been obvious to provide the desired therapeutic effect.

Response to Arguments

4. Applicant's arguments filed 17 June 2002 have been fully considered but they are not persuasive.
5. While Jacobs teaches an inflatable bladder to normalize the forces applied, there is no claim language to define over this. It may be true that Jacobs teaches a single inflation bladder to evenly distribute the pressure applied to the limb, the claims do not exclude this added feature of Jacobs. It remains a fact that Jacobs teaches that wound dressings can be used in combination with their device. While the wound dressing of Thorn may teach a type of wound dressing that very few are in use, it is still one type of wound dressing that is well known and could be used. The inflatable bladder may apply pressure to the wound dressing however, the purpose of the porous layer 7 is to maintain the outer layer 8 in spaced relation to maintain the vacuum pressure above the wound. One would not be destroying either teaching. One is just taking the suggestion of Jacobs to use a wound dressing with the inflatable bladder and using the wound dressing of Thorn to complete the apparatus.

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Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

ddd
17 October, 2002
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Danton DeMille
Primary Examiner
Art Unit 3764

No. 3627 P. 29
received
 3-13-03



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.1	8678

30159 7590 03/03/2003

ATTN: LEGAL-MANUFACTURING
 KINETIC CONCEPTS, INC.
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EXAMINER

DEMILLE, DANTON D

ART UNIT PAPER NUMBER

3764

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

VAC.331A. US

DOCKETED

FOR: Office Action
Response due 6-3-03

DOCKETED BY: S

Office Action Summary

Application No.

09/458,280

Applicant(s)

VOGEL ET AL.

Examiner

Danton DeMille

Art Unit

3764

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- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

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- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
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- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Notice of References Cited	Application/Control No. 09/458,280	Applicant(s)/Patent Under Reexamination VOGEL ET AL.	
	Examiner Danton DeMille	Art Unit 3784	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,222,478	06-1993	Scarberry et al.	601/44
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
 PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 15

PAGE 31/93 * RCVD AT 9/20/2006 1:00:12 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/22 * DNIS:2738300 * CSID:210 255 6969 * DURATION (mm-ss):32-14

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Application/Control Number: 09/458,280

Page 2

Art Unit: 3764

DETAILED ACTION***Claim Rejections - 35 USC § 103***

1. **Claims 1-5, 10-13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Thorn et al. and Scarberry et al.**
2. Jacobs teaches a foot wrap having an inflatable bladder for applying compressive force over the lower leg and foot of a patient. Jacobs also teaches that the foot wrap can be used in combination with a wound dressing column 6, lines 4-7. Clearly the inflatable bladder of Jacobs is capable of overlapping at least a portion of the wound dressing since it is taught that the releasable securing means allows the patient to take the device off to access the wound dressing. Thorn teaches a conventional wound dressing for introducing negative pressure over any area of the patient. Thorn uses a porous material as the first layer 7 and uses felt as an example material. There is no unobviousness to use any other equivalent porous material as an obvious equivalent alternative. Felt is not the only material that can be used. Scarberry teaches a wrap system that also applies a vacuum to a portion of the body and uses open celled foam as the first layer. Clearly open celled foam is an obvious equivalent alternative material to the felt of Thorn. It would have been obvious to one of ordinary skill in the art to modify Jacobs to use the foot wrap in combination with a wound dressing as taught by Thorn in order to complement the teaching of Jacobs and use open celled foam as taught by Scarberry as an obvious equivalent alternative material to the felt of Thorn to maintain the vacuum pressure over the wound. The free and open arrangement of the Jacobs wrap allows free placement of the wound dressing anywhere desired or required. Regarding claim 13, Thorn teaches a layer 7 of porous material. The porous material can be of any well known design as long as it maintains the space between the skin and

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Page 3

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the second layer 8. Open celled elastic foam is just such a conventional material and an obvious provision.

3. **Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tumey et al. in view of Thorn, Scarberry et al. and Jacobs et al.** Tumey teaches a foot wrap having an inflatable bladder for applying a compressive force to the patient's foot. Jacobs teaches the convention of using wound dressings in combination with inflatable foot wraps and Thorn exemplifies wound dressings that apply a negative pressure. Scarberry teaches the open celled foam as an obvious equivalent alternative material for the felt of Thorn. It would have been obvious to one of ordinary skill in the art to modify Tumey to include a wound dressing with the wrap as taught by Jacobs to be able to additionally treat wounds and to use the specific type of wound dressing as taught by Thorn as an obvious example of wound dressings with open celled foam as the first layer spacing material as taught by Scarberry as an obvious equivalent alternative. Tumey additionally teaches the convention of pressure sensors 47 to control pressurization. Tumey teaches the pressure source is intermittently operable. Thorn teaches the vacuum source can be operable to vary the negative pressure in a preprogrammed manor to provide the desired effect. The art teaches intermittent pressure application therefore providing intermittent negative pressure would have been obvious to provide the desired therapeutic effect.

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US005222478A

United States Patent [19]

Scarberry et al.

[11] Patent Number: 5,222,478
[45] Date of Patent: Jun. 29, 1993

[54] APPARATUS FOR APPLICATION OF PRESSURE TO A HUMAN BODY

[76] Inventors: Eugene N. Scarberry, 208 Terrace Ct. Rd., Trafford, Pa. 15085; Patrick M. Handke, 416 Brumar Dr., Monroeville, Pa. 15146

[21] Appl. No.: 895,225

[22] Filed: Jun. 8, 1992

Related U.S. Application Data

[63] Continuation of Ser. No. 412,627, Sep. 27, 1989, abandoned, which is a continuation-in-part of Ser. No. 273,587, Nov. 21, 1988, abandoned.

[51] Int. Cl.³ A61H 31/02

[52] U.S. Cl. 128/30.2; 128/28; 128/30

[58] Field of Search 128/28, 30, 30.2, 24 R, 128/DIG. 20, 206.21, 206.24, 206.25, 206.26; 602/13

[56] References Cited

U.S. PATENT DOCUMENTS

2,241,444 5/1941 Bower .
2,309,361 1/1943 Terhaar 128/30.2
2,480,980 9/1949 Terhaar .
2,899,933 8/1959 Huxley, III et al. .
3,043,292 7/1962 Mendelson 128/30.2
3,078,842 2/1963 Gray .

3,212,497 10/1965 Dickinson 128/DIG. 20 X
3,577,977 5/1971 Ritzinger, Jr. et al. .
3,745,998 7/1973 Rose .
4,257,407 3/1981 Macchi .
4,366,815 1/1983 Broomes .
4,508,112 4/1985 Sealer .
4,523,579 6/1985 Barry .
4,617,921 10/1986 Sealer .
4,621,621 11/1986 Maralis .
4,657,003 4/1987 Wirtz 128/869
4,664,098 5/1987 Woudenberg et al. .
4,739,755 4/1988 White 128/206.12

FOREIGN PATENT DOCUMENTS

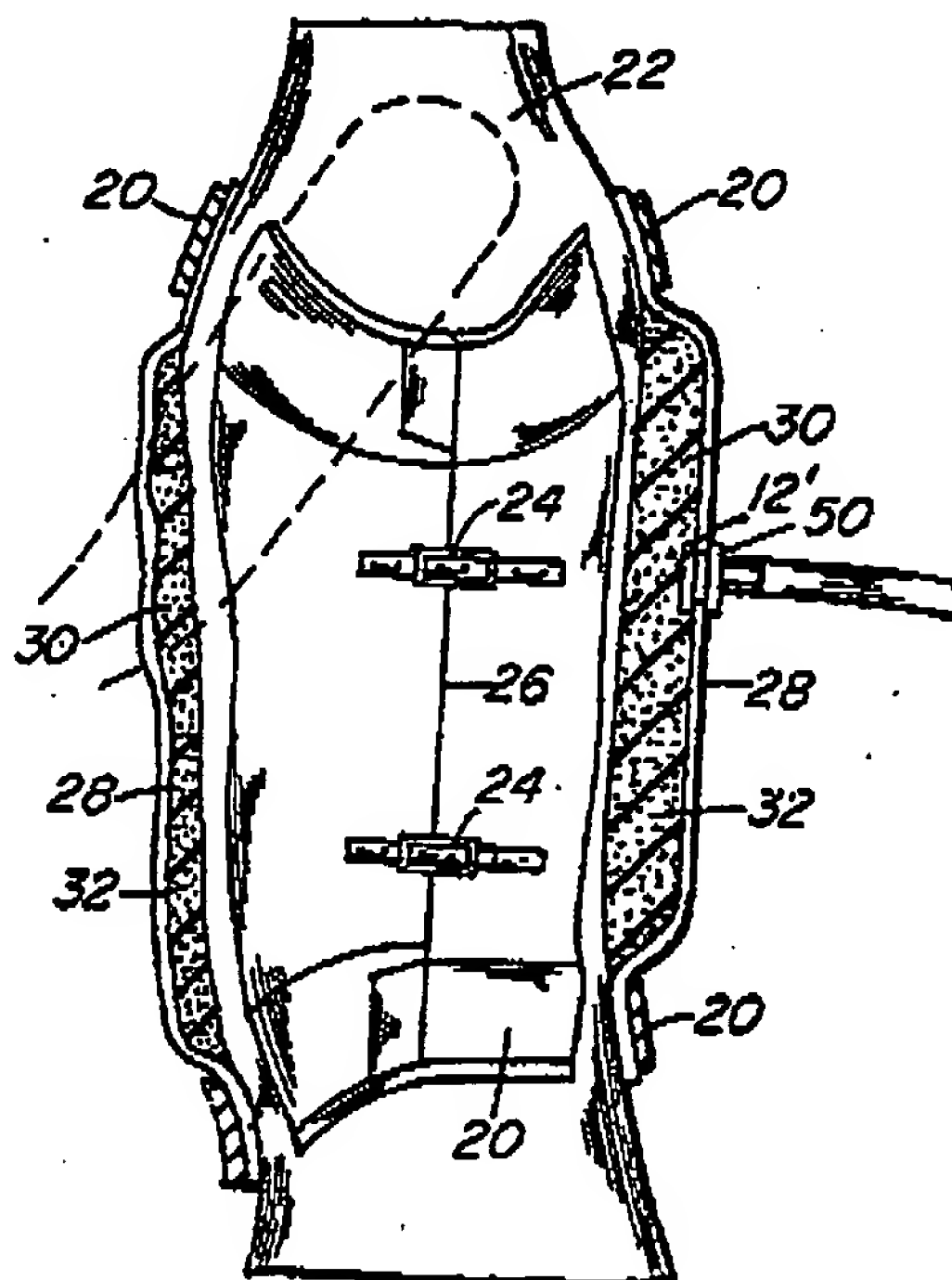
2635454 2/1990 France 606/53

Primary Examiner—Richard J. Apley
Assistant Examiner—Linda C. M. Dvorak
Attorney, Agent, or Firm—J. Stewart Brams

[57] ABSTRACT

A respirator, resuscitator, wrap or sheath, breathing mask or the like which provides a closely form-fitting shell adapted to be disposed adjacent a portion of a human body to form intermediate the shell and the human body portion a thin section, minimal volume pressure containment chamber which receives pressures varying from ambient pressure for therapeutic purposes, and a corresponding method.

30 Claims, 2 Drawing Sheets

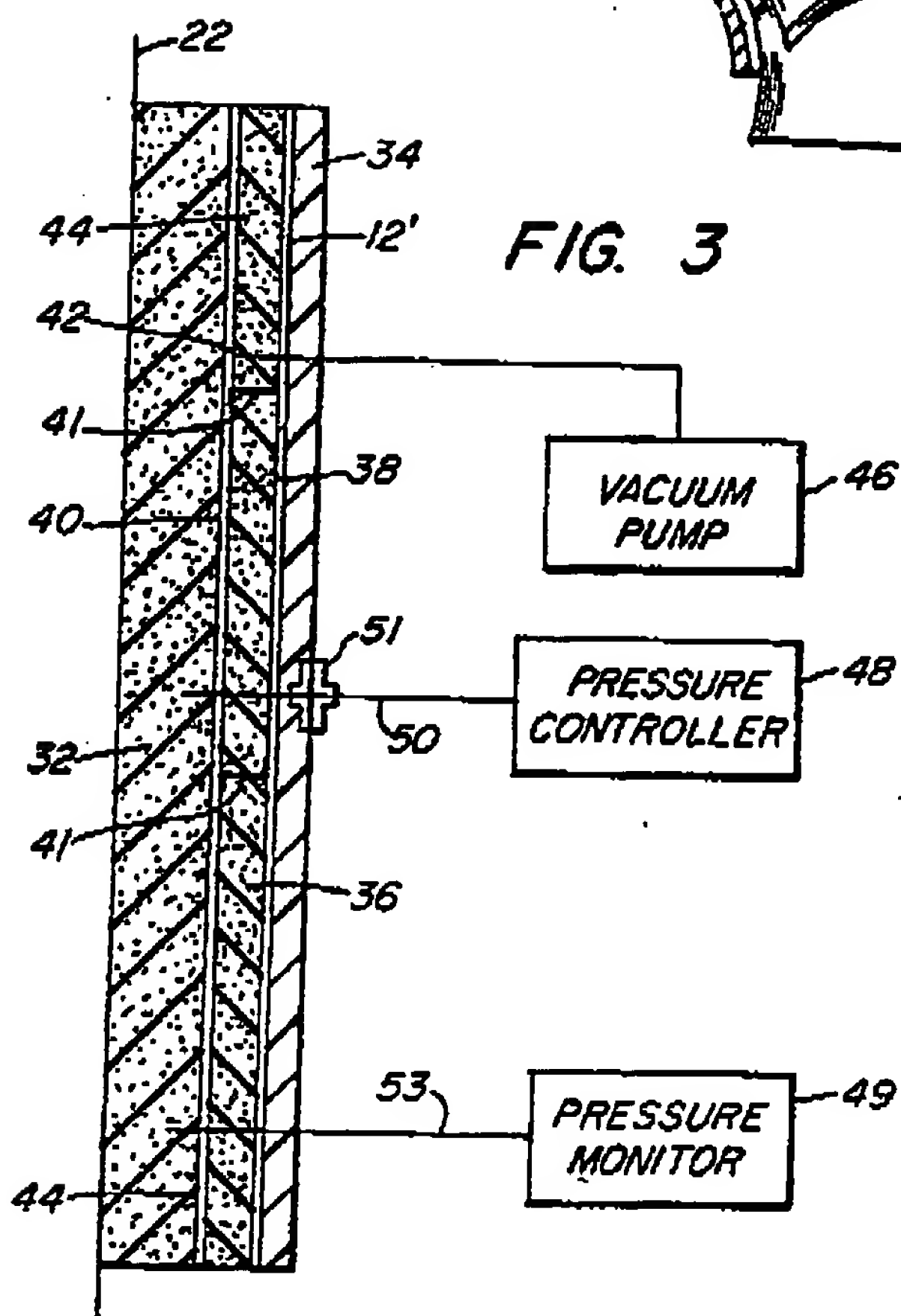
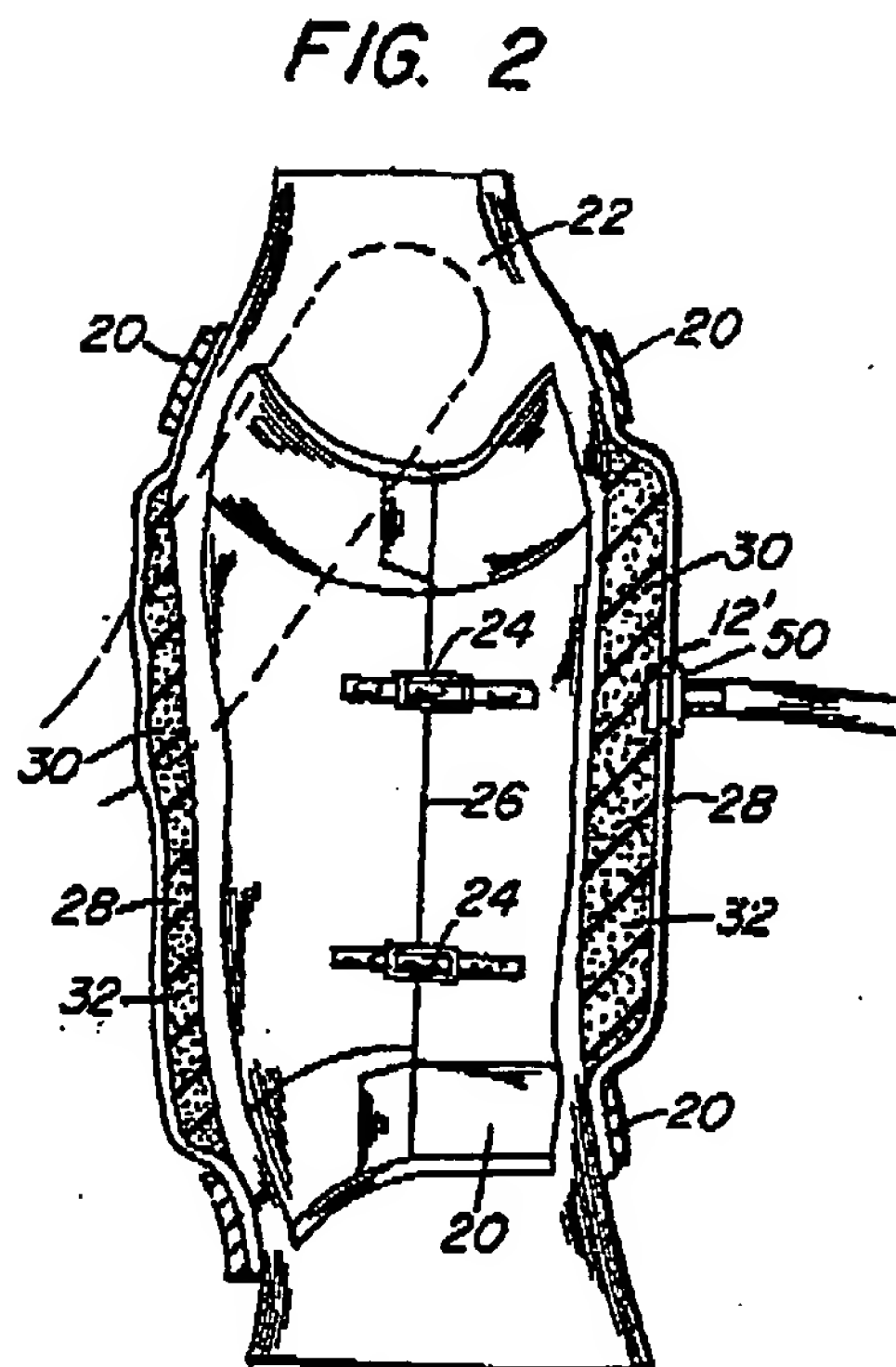
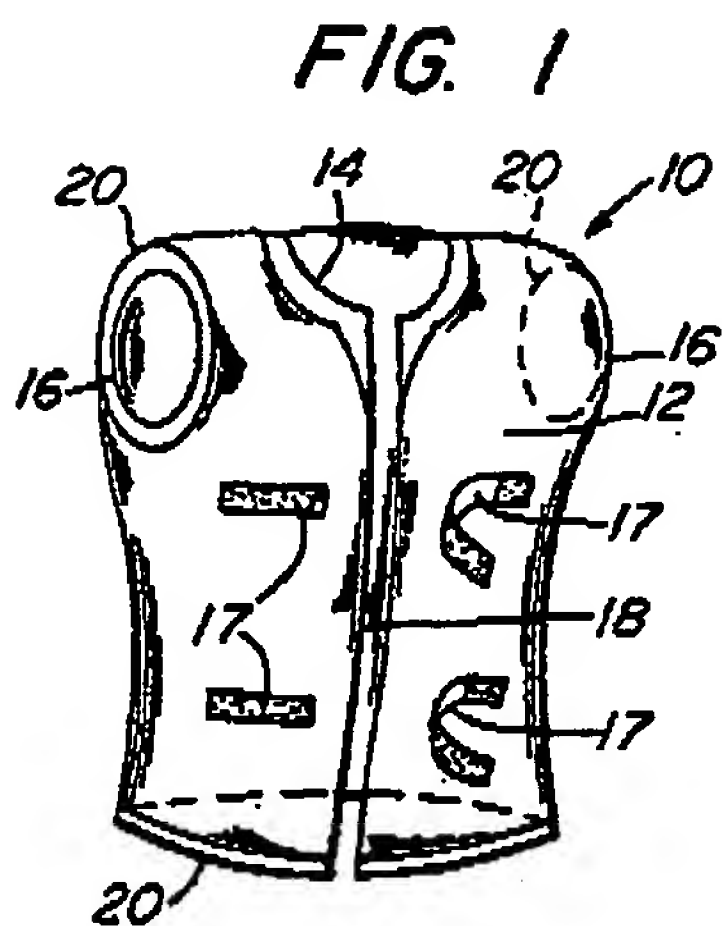


U.S. Patent

June 29, 1993

Sheet 1 of 2

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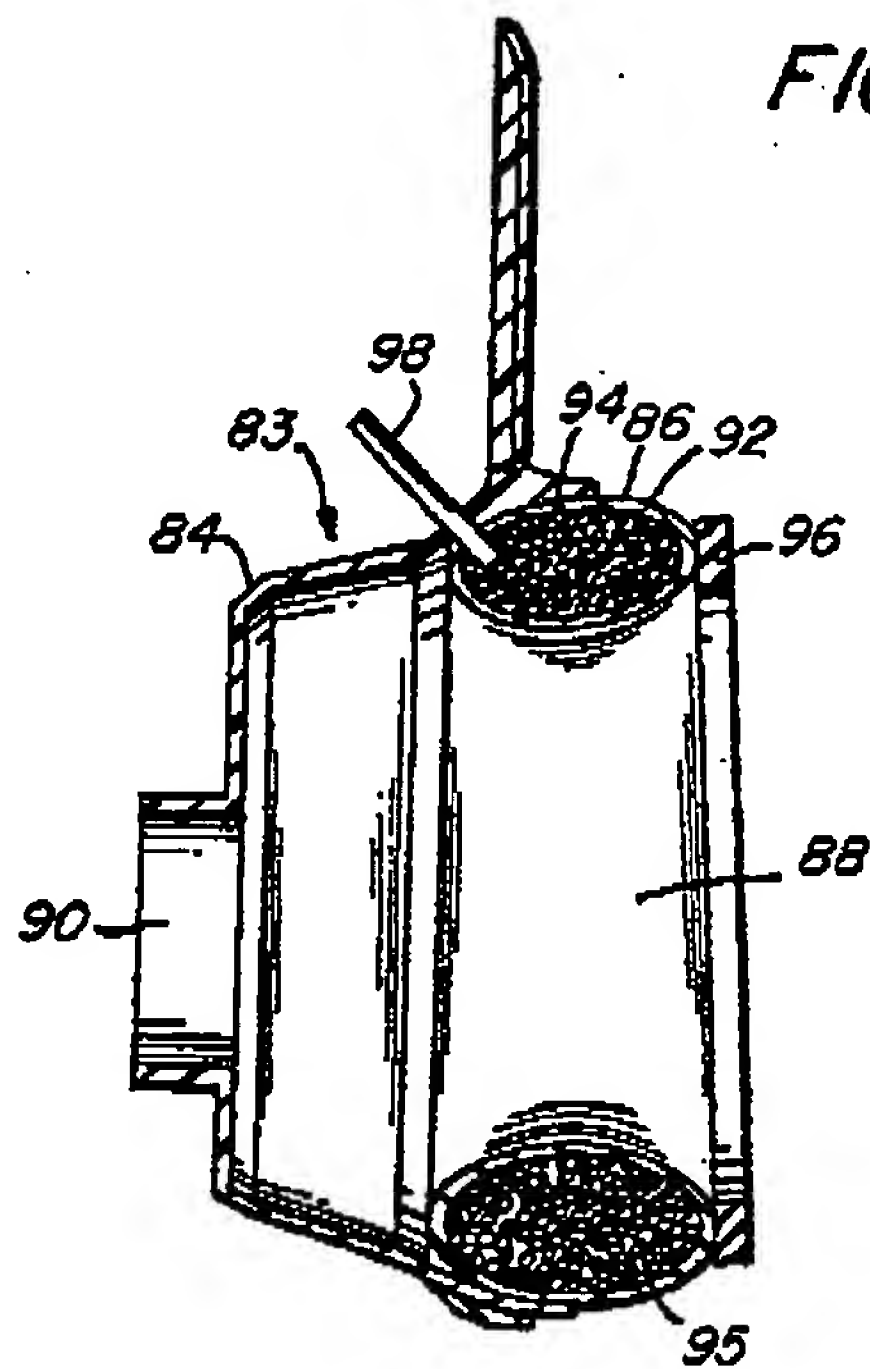
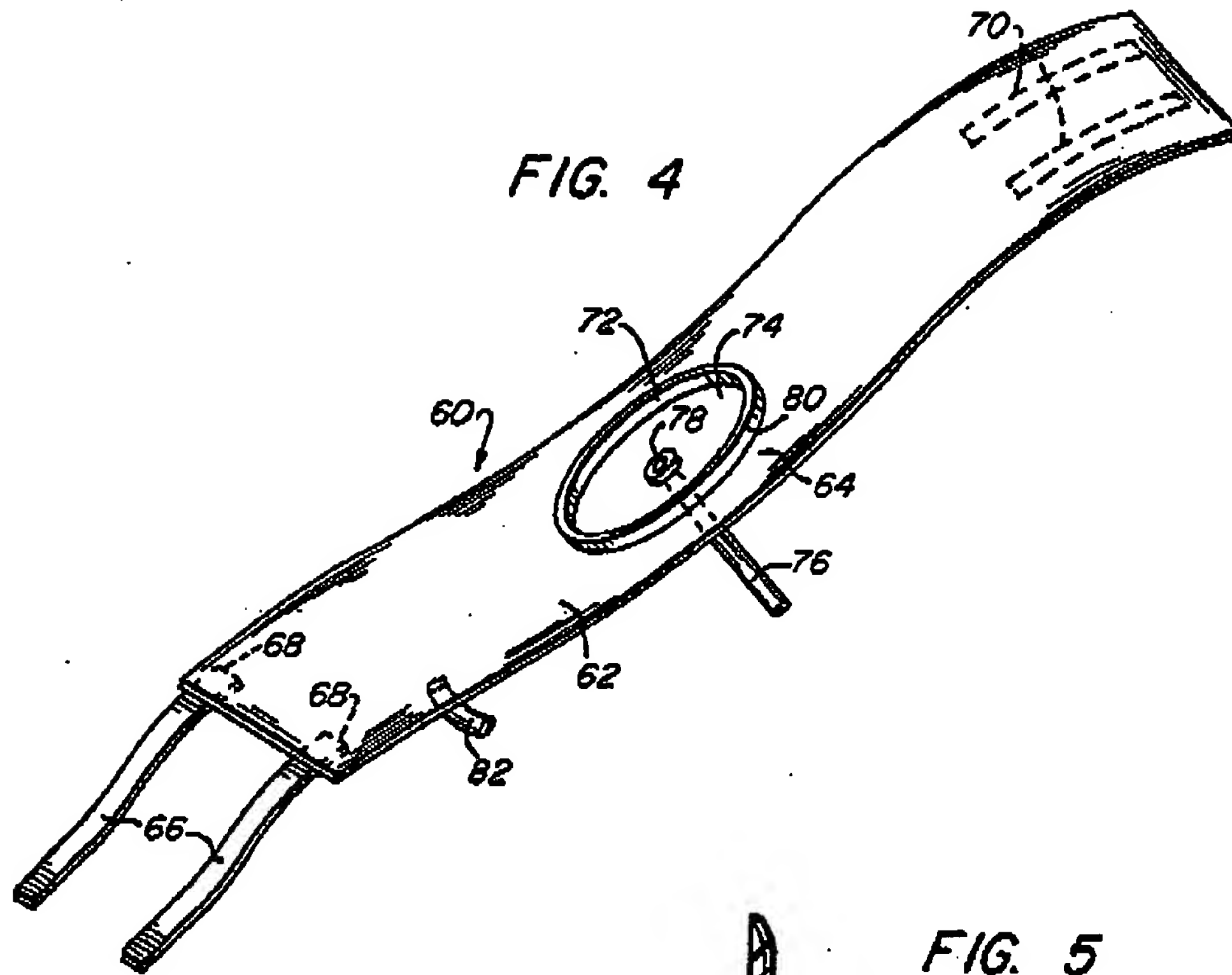


U.S. Patent

June 29, 1993

Sheet 2 of 2

5,222,478



5,222,478

1

APPARATUS FOR APPLICATION OF PRESSURE TO A HUMAN BODY

This application is a continuation of co-pending application Ser. No. 07/412,627 filed on Sep. 27, 1989, now abandoned which is a continuation-in-part of application Ser. No. 07/273,587 filed Nov. 21, 1988, now abandoned.

BACKGROUND OF THE INVENTION

In the art of respirators, resuscitators, and the like it is well known to provide apparatus in the form of an enclosure which encompasses a portion of the human body such as the upper torso or thoracic region thereof to provide within the confines of the enclosure a pressure containment chamber wherein pressure variations may be applied to the body to stimulate respiration. A wide variety of such devices are known, the following prior art being representative.

U.S. Pat. No. 3,078,842 discloses a resuscitation apparatus which employs a rigid shell to enclose the torso of a human body. U.S. Pat. No. 4,523,579 discloses another rigid shell type body respirator having flexible side walls. U.S. Pat. No. 2,241,444 discloses a respirator jacket comprised of a rigid shell made by laying up reinforced plaster of paris material on a plaster cast which has been molded to the body contours of the individual user, and which includes an enlarged cavity confronting the chest and adjacent abdominal region of the user. Other rigid shell type resuscitators are disclosed by U.S. Pat. No. 4,257,407 and 2,309,361. The latter of these discloses a padded liner in a rigid generally form-fitting respirator.

U.S. Pat. No. 2,899,955 discloses a respirator belt which encircles the waist of a user and includes an inflatable bladder to which air pressure is directed for assisted breathing. U.S. Pat. No. 4,621,621 discloses a respirator including a rigid wire cage that encompasses a portion of a user's body and is in turn encompassed by an air tight cover to provide a vacuum chamber surrounding the user's body. U.S. Pat. No. 3,577,977 discloses a flexible, inflatable bladder-type jacket and U.S. Pat. 2,480,980 discloses a rigid, generally form-fitting respirator jacket. Finally, U.S. Pat. No. 4,664,098 discloses a cardio-pulmonary resuscitator which is worn by a patient in the manner of a belt encompassing the abdominal region.

Notwithstanding such known devices, practitioners in the art have continued to seek improved body respirators. For example, improvements have been continually sought in body respirator compactness, portability, user comfort, reduced power requirements, and of course improved therapeutic efficacy.

Also known in the prior art are a variety of vacuum devices for immobilizing a part of a body. The Rapid Form TM brand vacuum splint is one example. Such devices utilize a structure known as vacuum beads to provide a selectively rigid or flexible member that is used, for example as in the case of the above specified vacuum splint, to immobilize selected body parts that have sustained bone fractures or the like. Such known devices generally comprise a thin section airtight envelope filled with material such as styrofoam beads which interengage and deform upon application of a vacuum within the envelope to thereby render the vacuum bead material relatively rigid. The rigid vacuum bead material thus is utilized to immobilize a selected body part.

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BRIEF SUMMARY OF THE INVENTION

The present invention contemplates a novel and improved body respirator, resuscitator, pressure or pulse monitoring apparatus or similar apparatus such as a wrap or sheath, or a breathing mask which is universal in its application by virtue of its being very closely form-fitting for any selected user irrespective of variations in body size or contours from one user to another.

The invention also is light in weight and compact, imposes minimal power requirements for its use, and provides greatly enhanced user comfort and therefore enhanced user tolerance. The invention thus provides greatly enhanced convenience for the user as well as for emergency rescue teams and others who may encounter the need for regular access to emergency equipment of this sort, among other advantages. The invention also contemplates a novel and improved method for the use of varying pressures in a variety of medical applications.

The apparatus of this invention contemplates, in one of several presently preferred embodiments, a body enclosure comprised of a sheath or wrap of selectively flexible or rigid material, such as the above characterized vacuum bead structure or the like, formed to encompass a selected body portion and including seals to seal perimeteral portions or other portions of the body sheath, for example to seal about the openings through which adjacent body portions project such as at the waist, neck, or arms.

The sheath is adapted to be placed in closely spaced form-fitting relation encompassing a portion of the user's body to define, in a zone between the sheath and the user's body, a very thin-section chamber or space. The sheath is then selectively rigidified, as by application of a vacuum if comprised of conventional vacuum bead material, to form a rigid, form-fitting enclosure about the encompassed portion of the patient's body whereby the chamber or space between the sheath and the user's body is provided with a rigid outer wall which closely conforms to the adjacent body contours of the user. Pressure or vacuum generating equipment may be utilized to apply pressure variations within this space to act on the flexible inner wall (i.e. the user's body) to assist user ventilation or for other purposes. Alternatively, the pressure within the space may be observed to monitor user pulse, breathing, or the like.

Because the sheath is selectively rendered rigid or flexible, it is quite compact and easily stored when not in use. Because it is placed about the user's body in a flexible state, it is universal in application and extremely closely form fitting with the attendant benefit that the containment space defined between the sheath and the user's body is of minimal volume. Effective operation thus is achieved with minimal power requirements and minimal required compressor or vacuum pump delivery rates.

The invention additionally contemplates spacer means disposed within the pressure containment space between the sheath and the user's body so as to define a predetermined minimal spacing therebetween so that the form and volume of the pressure containment space may be readily controlled. The spacer means is of a structure (e.g. open cell foam) to permit pressure variations introduced at one point within the containment space to be transmitted throughout the space even if the spacer means is substantially co-extensive with the pressure containment space.

5,222,478

3

The invention additionally contemplates a novel and improved method of fluid pressure utilization in conjunction with the body of a user with advantages corresponding to the above noted and other advantages of the novel apparatus.

It is accordingly one object of our invention to provide a novel and improved body respirator, resuscitator, or the like.

It is a further object of our invention to provide an improved apparatus and method for the utilization of external pressure in the medical treatment of a patient.

A more specific object of the invention is to provide a selectively rigid or flexible body wrap sheath, mask, vest, or similar apparatus which is adapted to encompass a portion of a body to thereby define in conjunction therewith a sealed space adjacent the body such that pressure controlling or monitoring means cooperable with the sheath is operable to selectively vary or monitor the pressure within the sealed space.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects and further advantages of my invention will be more readily understood upon consideration of the following detailed description and the accompanying drawings, in which:

FIG. 1 is a frontal elevation of one presently preferred embodiment of our invention;

FIG. 2 is a side elevation, partially broken away to show details of an alternative embodiment of our invention shown encompassing the body of a user;

FIG. 3 is an enlarged detailed portion of FIG. 2 including schematic representation of a vacuum pump and pressure controller according to one presently preferred embodiment of the invention;

FIG. 4 is a perspective view of a wrap or sheath apparatus according to an alternative embodiment of the invention; and

FIG. 5 is a sectioned side elevation of a breathing mask or similar apparatus according to another alternative embodiment of the invention.

There is generally indicated at 10 in FIG. 1 a body respirator or the like constructed according to one presently preferred embodiment of our invention and including a body sheath 12 formed for purposes of this embodiment as a vest or jacket and including, when enclosed about the user's body, a neck opening 14 as well as arm holes or apertures 16.

Suitable fasteners are provided, for example Velcro™ or similar interengaging tapes, to maintain a front opening 18 tightly closed and sealed when the vest is donned and in use, and to thus maintain the sheath 12 in closely form-fitting relation about the upper torso or thoracic region of the user's body.

An alternative form of the sheath or vest as identified at 12' in FIG. 2 passes beneath the arms of the user so no arm holes are required. The sheath 12' encompasses the user's waist and upper chest. For the embodiments shown in FIGS. 1 and 2, all openings from which parts of the user's body project are sealed by suitable seal means such as encompassing band means 20 to form intermediate the sheath and the body 22 (FIG. 2) of the user a sealed space or chamber 32.

Other differences of the FIG. 2 embodiments from that of FIG. 1 include buckle and strap fasteners 24 in lieu of fasteners 17 and the location of closure 26 adjacent one side of the user's body rather than extending vertically along user's front as does opening 18 of the FIG. 1 embodiment. Of course, a wide variety of alter-

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native configurations may be utilized in accordance with the specific purposes and desired features of the sheath 12. Specifically, an apparatus according to this invention but adapted to encompass a body part other than the chest or abdominal region will of course be configured accordingly.

Regarding further aspects of the invention, as exemplified by FIG. 2, sheath 12' comprises a selectively rigid or flexible wall system 28 which is maintained in closely spaced relationship with respect to the user's body 22 as by means of spacers 30, which may be of such suitable structure as open cell foam to permit the transmission of pressure variations imposed at one location within the confines of the sheath 12' to all locations therein.

The spacers 30 may occupy only a small portion or alternatively substantially all of the volume of the space 32 defined intermediate sheath 12' and the user's body 22, within the confines of perimeteral seals 20. It will be noted, however, that space 32 need not be coextensive with the mutually contiguous zones of sheath 12' and the user's body 22, that spacers 30 may be of other suitable structure or may be eliminated entirely, and that seals 20 need not be disposed about perimeteral portions of the sheath 12' where portions of the user's body extend therefrom.

The invention thus contemplates an apparatus which is utilized to form a sealed space between a body sheath and a user's body with the sealed space being defined generally by an inner wall system comprised of a portion of the user's body, an outer wall system comprised of a corresponding adjacent portion of a sheath wall disposed in closely spaced form-fitting relation with respect to the user's body. A seal system seals all interfaces between the sheath and the user's body that are exposed to pressure variations introduced within the sealed space.

It is noted that seals are to be provided to seal any opening which is provided to facilitate installation or removal of the sheath, for example opening 18 of FIG. 1 or 26 of FIG. 2. These and any other such openings would require seals to preclude leakage due to a pressure differential between ambient and the pressure condition within space 32.

There is shown in FIG. 3 a portion of my novel body respirator. In FIG. 3, sheath 12' is comprised of an outer flexible shell 34 of sheet polyethylene for example, which is coextensive with the selectively rigidified structure 36. Structure 36 comprises a pair of flexible, closely spaced, air impermeable inner and outer walls 38 and 40 of such suitable material as vinyl or polyurethane impregnated nylon. The inner and outer walls 38 and 40 are sealed together along a continuous line encompassing a space 42 therebetween, which space 42 contains a mass of interengageable elements 44 such as beads of styrofoam plastic. Air permeable partition elements 41 joined to and extending between walls 40 and 38 may be provided at intervals in space 42 as barriers to prevent undesirable migration of beads 44 within the space 42.

As is known, the above described structure is typical of vacuum bead type systems wherein the application of a vacuum within space 42, as by means of a vacuum pump 46, causes walls 40 and 38 to collapse inwardly under the impetus of external ambient air pressure against the beads 44. Thus, upon imposition of such a vacuum in space 42, the styrofoam beads 44 deform in interengagement and lock up in an immobilized state to

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form a rigid shell from the previously flexible shell. Upon release of the vacuum drawn within space 42, the styrofoam beads 44 are released from their mutual inter-engagement and the vacuum bead structure 36 becomes once again flexible.

Carried adjacent the inner wall 40, and preferably affixed thereto in a suitable manner is the spacing material 32 as above characterized. In use, the innermost extent of the spacing material 32 engages the body of the user 22 to thereby establish and maintain a generally uniform spacing or separation between the sheath 12' and the user's body 22.

Of course, the spacing therebetween is uniform only if the spacer element 32 is of uniform thickness. More generally, the spacing between sheath 12' and user's body 22 may vary according to variation in the thickness of the spacing elements 32. Also, and as noted hereinabove, the spacing element 32 may be omitted entirely as it is contemplated that only a very thin section space generally is necessary between the user's body and the sheath 12' for effective operation of the invention.

As further shown in FIG. 3, the invention additionally comprises a pressure controller 48 which is powered by any suitable and conventional power means to deliver air flow under pressure to space 32 in order to impose within space 32 controlled pressure at variance with ambient atmospheric pressure. For example, pressure controller 48 may be utilized to impose alternating or cyclic elevated pressure within space 32, or a partial vacuum.

In order to accommodate the pressure controller 48, a suitable air flow delivery conduit 50 provides an air flow path between pressure controller 48 and space 32, and of course therefore traverses the sheath 12'. In a preferred embodiment the sheath 12' will include a port means having any suitable, known coupling 51 or air conduit connection on the outer side thereof for connection to a delivery conduit from pressure controller 48.

For emphasis it is reiterated here that the apparatus of this invention may take any of a variety of forms to encompass any portion of a user's body other than the chest or thoracic region and for a variety of purposes other than respiratory assistance. For example, an apparatus similar in many salient respects to that above described and encompassing the thoracic region may be utilized with alternating pressure, and in conjunction with alternating pressure delivered in a specified phased relationship to the airway of a patient to function as a heart pump for cardio-vascular resuscitation. In another alternative mode of use, the apparatus of this invention may be utilized with pressure monitoring equipment 49 (FIG. 3) which is connected via a conduit 53 to space 32 for the purpose of monitoring pressure therein. Thus any physical response of a user which causes variation of the pressure within space 32, pulse or spontaneous breathing for example, may be observed by use of pressure monitor 49. The invention may also be embodied as a wrap or sheath as above mentioned, for example a wrap or sheath for a limb or other extremity. In FIG. 4 I have shown such a wrap or sheath 60 which is adapted to encompass a human limb or any similarly configured body part, for example, the neck. The sheath 60 is comprised of an elongated flexible band 62 which forms an elongated, thin section envelope 64 that contains therein material such as styrofoam beads similar in all salient respects to the above described vacuum bead structures.

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Fastener bands 66 are affixed adjacent one longitudinal end of band 64 as by stitching 68 and cooperating fastener strips 70 are similarly affixed adjacent the opposed end of band 62. Fastener strip 66 and 70 may be cooperating hook and loop type fastener strips such as Velcro™ brand fastener material.

Sheath 60 may also include seal means such as a patch seal 72 in the form of a foam rubber or similar sealing strip affixed to one side of band 62 intermediate its longitudinal ends and forming thereon a closed perimeter which defines within its confines a space 74. A suitable vacuum connection 76 communicates with space 74, for example by penetrating the band 62 via a fitting 78 within the confines of seal 72. The sheath 60 thus may be applied to a human limb or similarly configured body part as a wrap with the fastener strips 66 and 70 overlapping to maintain the band 62 in encompassing relationship on such a body part and with an outer seal surface 80 of seal member 72 engaging a corresponding surface portion of such body part continuously along the extent of seal 72. By application of vacuum as via a vacuum connection 82, the band 62 may be selectively rigidified in encompassing relationship about a human limb as described. In an alternative embodiment, the selectively rigidified part of band 62 may be limited to that part encompassed by seal 72.

For either embodiment, the application of vacuum to the band 62 as described forms a relatively rigid outer wall for space 74 with the inner wall thereof being that portion of the patient's body encompassed by seal 72. Accordingly, pressures varying from ambient atmospheric pressure may be applied for therapeutic effect to that portion of the patient's body exposed to such pressure variation within the confines of seal 72 in much the same manner as pressure variations are applied to the upper thoracic region as above described with reference to FIGS. 1 through 3.

Specifically, since the outer wall of space 74 is rigid, the application of elevated pressure above ambient pressure via connection 76 in space 74 will tend to compress the corresponding adjacent portion of the patient's body which forms the inner wall of space 74 whereas a partial vacuum within space 74 will tend to distend the adjacent body portion by drawing it into the space 74.

Another alternative embodiment of the invention is shown in FIG. 5 as a breathing mask 83 having a generally rigid body 84 which carries a seal assembly 86 that encompasses an open space 88 which communicates through body 84 with a gas supply connection portion 90 of mask body 84. Accordingly, mask 83 may be placed with seal assembly 86 in confronting engagement with a user's face so that seal assembly 86 encompasses the nose or the nose and mouth of a user. Breathing gas for the user is then supplied exclusively through connection 90.

Since the function of a breathing mask such as shown in FIG. 5 differs from the function of a body type respirator such as shown in FIGS. 1 through 3, the expanse of space within the confines of seal 86 need not be enclosed by the vacuum bead material to provide a rigid outer wall such as is required for the respirator of FIGS. 1 through 3. Rather, for the FIG. 5 embodiment of the invention, the function of vacuum bead structure as described hereinbelow is to provide an effective and closely conforming surface seal to fit a wide variety of user facial contours in more or less universal fashion whereby a single mask may be readily adapted for use by virtually any patient.

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Accordingly, it will be seen that seal assembly 86 comprises a flexible perimetral wall system 92 comprised of rubber for example, and formed in a closed ring with a generally tubular cross section. The space 94 closed within the wall system 92 is filled preferably with vacuum bead material such as above described with reference to FIGS. 1 through 3, for example styrofoam plastic beads.

The resilient wall element 92 is mounted upon mask body member 84 and extends outwardly therefrom, and a seal member 96 may be affixed to an outer extent of wall element 92 for confronting sealing engagement with a user's face. A vacuum connection 98 is provided to permit drawing a partial vacuum upon space 94 with seal 96 in engagement with that portion of a user's face encompassing the nose or the nose and mouth. The partial vacuum, acting on the mass of interengageable beads, causes them to become forcefully interengaged under the impetus of ambient atmospheric pressure compressing the flexible wall element 92 inwardly. The mass of beads thus becomes rigid and supports the wall 92 against inward collapse. The wall 92 thus holds whatever form it and the contained beads have assumed by virtue of sealing pressure against the face of a user. Accordingly, the mask 83 is effective universally for any user as the seal thereon readily conforms, and is maintained in conforming relationship to the user's face by virtue of operation of the vacuum bead apparatus as described.

For purposes of this invention, including all embodiments described hereinabove, the structure of the vacuum bead material may include a variety of alternatives including styrofoam beads as above described or alternatively a finely divided powder with similar mechanical properties. Additionally, the material within the vacuum envelope may be infused or coated with a bonding agent such as a heat curing adhesive to permit the set or shape of the vacuum bead structure, once established by the vacuum action, to be permanently maintained. This is done by subjecting the vacuum bead material to sufficient activating or curing energy such as heat for curing a heat cured adhesive. Other types of bonding systems may also be used, for example chemical curing systems pressure sensitive adhesives, photo sensitive or light curing systems, and so forth. Any adhesive will suffice which provides the function of maintaining the shape or form of the vacuum bead structure after release of the vacuum by bonding the individual vacuum beads or similar elements together. Some adhesive systems, such as heat curing or heat setting adhesives, would for all practical purposes be limited to use in a structure as described which is to be permanently maintained in the form suited to a particular user. That is, once the heat setting adhesive is cured, it would not be possible to re-use the same adhesive. By contrast, a hot melt adhesive or similar bonding system would permit re-use of a mask or respirator structure according to this invention for another user as the bonds between interengaged vacuum beads could be broken by mechanical force (i.e. massaging or kneading the vacuum bead envelope). The mask or respirator could then be fitted to a different user, the vacuum applied to maintain the resulting seal and/or space configuration, and the vacuum bead material then once again subjected to heat to melt the adhesive and bond the vacuum bead materials in the new configuration.

The seal 96 of FIG. 5 or corresponding seal elements from other disclosed embodiments similarly may take a

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variety of forms including a rubber surface seal as shown, or alternatively an inflated bladder seal filled with air, foam or gel, a flap seal, or the like. Any of these may include a tacky outer surface for engagement with the respective body part of a user to provide sealing with a user's body in part by temporary, releasable adhesion to the skin. Another seal structure contemplated includes a closed envelope containing a hydroscopic gel material which has cushioning properties and a tacky character such that the seal is resilient at low mechanical loads but is permanently deformed by larger loads. The air filled bladder seal generally may be a tubular bladder with air space encircling a space similar to 94 that contains therein vacuum bead material or any alternative as above discussed. In addition, it is contemplated that the outer surface of wall 92 may function itself as a seal for confronting engagement with a body portion of a user such that a separate seal member such as at 96 in FIG. 5 may be entirely eliminated.

In an additional alternative embodiment applicable to any of the above described structures, the invention may be comprised of a body member which carries a separate, replaceable vacuum bead liner structure as opposed to having the vacuum bead structure permanently installed with other elements of the invention.

One advantage of the mask structure of FIG. 5 is that when vacuum is applied via connection 98, the vacuum bead material 95 will be maintained in a rigid form defining an outer profile for sealing in close conformity to the face of a user; however, if leaks should be present in such a seal, the vacuum bead material 95, even when under vacuum, can be formed or molded by the application of mechanical pressure (i.e. finger pressure) to change the seal profile or configuration. Accordingly, if leaks are detected after application of vacuum, the medical practitioner can eliminate such leaks with mere finger pressure applied against wall element 92 adjacent the leak. Such mechanical pressure will displace the wall 92 inwardly thus moving or displacing the immediately adjacent vacuum beads. Since under such relatively small and non-uniform mechanical pressures the individual beads are not significantly compressed but merely redistributed, mechanical finger pressure as described will force some of the vacuum bead material outwardly in the direction of seal 96 to thereby close the leak. Thus, with the combination of direct fitting to the face of the user, application of vacuum to maintain resulting shape, application of mechanical pressure as needed to effect proper seal conformity with the user's face, and finally application of heat or other mechanism to set an adhesive supplied within space 94 to the vacuum bead material 95, the mask 83 provides for a custom fit to any user, which custom fit is then maintained indefinitely for as long as that user must use the mask. The same mask may then be reused to fit any other user with a similar custom fit to provide seal integrity of equal quality.

In still another alternative embodiment of the invention, the vacuum bead material 95 may be supplanted entirely by a heat cure or similar adhesive in powder, granular or bead-like form. Although such a structure is believed to be less useful for repeated universal applications, it would be the equal of other above described embodiments for providing a closely conforming seal in a single use for any user irrespective of differences in facial contours.

Entirely similar structural alternatives as above disclosed also are contemplated for the embodiments of

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FIGS. 1 through 4 inclusive, and for still further embodiments not heretofore discussed. For example, the disclosed mask structure also contemplates such alternatives as a mask effectively functioning as a perime-
teral seal with nasal cannulae protruding within space 5 88 to be received into the nares of a user.

From the above description, our novel method will also be apparent as including, *inter alia*, the steps of encompassing or enclosing a patient's body portion with a flexible structure including a seal to provide 10 sealing against selected body portions to form a chamber or enclosed space, and rigidifying at least a part of the structure to provide a rigid boundary for a corresponding part of the enclosed space then one may, selectively vary the pressure condition within the enclosed space from ambient either at will or in a prede- 15 termined program of pressure variation, or by voluntary or involuntary patient response, and as a further optional step, such pressure variation occurring within the enclosed space may be monitored.

According to another aspect of our novel method, the encompassing of a patient's body portion with a flexible sheath as hereinabove specified may be per-
formed as a treatment for obstructive sleep apnea. Sleep apnea is a widespread sleep disorder estimated to affect 25 up to 3% or more of the general population and commonly characterized by occlusion of the upper airway in sleep with resultant disruption of breathing and sleep patterns, and potential serious consequences including oxygen starvation.

The method of our invention accordingly contem-
plates the application of negative pressure (i.e. pressure below ambient atmospheric) at least to frontal areas of a patient's neck to thereby draw out or distend the adja-
cent tissue thus permitting the relatively elevated ambi- 30 ent pressure in the airway, or artificially elevated pressure therein such as CPAP (continuous positive airway pressure), to expand or distend the upper airway thereby relieving airway occlusion.

According to the description hereinabove there is 40 provided by the instant invention a novel and improved method and apparatus for the external application of pressure variations to a portion of a user's body. The invention may be utilized to apply pressure at decreased or elevated magnitude with respect to ambient, or in a 45 program of varying pressure magnitudes applied by automatic or manual control, or even pressure variations from ambient or from elevated or decreased pressure magnitudes resulting from voluntary or involuntary user response. The invention further contemplates 50 the monitoring of any such pressure magnitude or variation thereof.

The invention also contemplates an apparatus com-
prised of separate inner garment, vacuum bead shell, and outer garment structures. The inner garment may 55 be, for example, a foam rubber shell bonded to a fabric backing for the purpose of separating the vacuum bead structure from the user's body. The outer garment may be of the character above described with reference to flexible shell 34, and may include all of the requisite 60 seals such as the described seals 20. Thus it will be clear that the above described components of the invention may be integrally formed together, formed separately and permanently or separably connected, or formed and used separately to make up a flexible body enclosing 65 sheath apparatus as above described.

I have contemplated various other alternative and modified embodiments apart from those specified here-

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inabove, and certainly such would also occur to others versed in the art once apprised of my invention. Accordingly, the invention is to be construed broadly and limited only by the scope of the claims appended hereto.

I claim:

1. An apparatus for applying external pressure variation to a given body portion of a user's body comprising:

a sheath means adapted to be retained with respect to the given body portion;

said sheath means including a flexible portion which is adapted to be formed into a selected shape which closely conforms with the given body portion to provide a closely form-fitting enclosure which envelopes the given body portion at essentially a minimum spacing therefrom when said sheath means is retained with respect to the given body portion;

said sheath means including seal means which is operable to engage the user's body to form within said form-fitting enclosure an enclosed space intermediate said sheath means and the given body portion; connection means communicating with said enclosed space and adapted to be connected to a pressure medium source for applying the pressure of a pressure medium at variance from ambient atmospheric pressure within said enclosed space; and

means operable for selectively rigidifying said flexible portion when retained with respect to the given body portion in a manner that upon said selectively rigidifying, said flexible portion is maintained in said selected shape to provide said closely form fitting enclosure at said essentially minimum spacing throughout application of pressure within said enclosed space.

2. The apparatus as set forth in claim 1 additionally including pressure control means cooperable with said sheath means to selectively vary the magnitude of pressure within said enclosed space.

3. The apparatus as set forth in claim 1 additionally including pressure transmitting spacer means cooperable with said sheath means to limit the approach of said flexible portion toward the given body portion and to thereby define said minimum spacing.

4. The apparatus as set forth in claim 3 wherein said spacer means is substantially mutually coextensive with said enclosed space.

5. The apparatus as set forth in claim 4 wherein said spacer means includes porous means having sufficiently open porosity to permit the pressure medium to be distributed substantially throughout said enclosed space.

6. The apparatus as set forth in claim 4 wherein said flexible portion is essentially coextensive with said sheath means.

7. The apparatus as set forth in claim 1 wherein said seal means includes means cooperable with said sheath means to maintain a selected portion of said sheath means in sealed engagement with the user's body to form said enclosed space.

8. The apparatus as set forth in claim 1 additionally including adjustable retention means which is cooperable with said sheath means to permit said sheath means to be retained with respect to the given body portion.

9. The apparatus as set forth in claim 1 wherein said means operable for selectively rigidifying said flexible portion includes a flexible, wall portion of said sheath means enclosing a sealed chamber and a plurality of

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interengageable elements confined within said sealed chamber, and means communicating with said sealed chamber and adapted to communicate with a vacuum pump means for drawing a partial vacuum within said sealed chamber to thereby engage said interengageable elements in essentially rigid mutual interengagement.

10. The apparatus as set forth in claim 9 additionally including an outer flexible wall portion which is coextensive with said flexible portion and said outer flexible wall portion carrying adjacent at least a portion of its perimeter a portion of said seal means.

11. The apparatus as set forth in claim 10 additionally including air flow conveying conduit means traversing said sheath means and cooperable with said pressure medium source to provide air flow to and from said enclosed space.

12. The apparatus as set forth in claim 1 additionally including pressure monitoring means cooperable with said sheath means to monitor the pressure within said enclosed space.

13. The apparatus as set forth in claim 1 wherein said sheath means comprises a respiratory assistance apparatus adapted to encompass the upper torso of a human body for application thereto of such pressure to effect respiratory assistance.

14. The apparatus as set forth in claim 1 wherein said sheath means comprises a resuscitation apparatus adapted to encompass the upper torso of a human body for application thereto of such pressure to effect cardiopulmonary resuscitation.

15. An apparatus for enclosing a selected body portion of a human body comprising:

an enclosing means which is adapted to confront the selected body portion;

seal means associated with said enclosing means and operable to encompass a peripheral extent of the selected body portion and to sealingly engage said peripheral extent in a manner to define an enclosed space which extends adjacent the selected body portion and is enveloped by said enclosing means; said enclosing means including a flexible portion which is adapted to be formed into a selected shape which closely conforms with at least a corresponding adjacent part of the selected body portion to provide a closely form-fitting enclosure which envelopes said corresponding adjacent part of the body portion at essentially a minimum spacing therefrom;

means operable for selectively rigidifying said flexible portion in a manner that upon said selective rigidifying said flexible portion is maintained in said selected shape; and

pressure medium connection means communicating with said enclosed space and adapted to be connected to a pressure medium source to provide within said enclosed space pressure at variance from ambient atmospheric pressure for application to the selected body portion.

16. The apparatus as set forth in claim 15 wherein said flexible portion includes a flexible wall means defining a sealed containment and a plurality of interengageable means disposed within said containment.

17. The apparatus as set forth in claim 16 wherein said means in rigidifying said flexible portion includes means for drawing a partial vacuum within said containment to permit ambient air pressure acting on said flexible

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wall means to move said interengageable means into mutual interengagement.

18. The apparatus as set forth in claim 17 additionally including adhesive means which is effective to maintain said interengageable means in mutual interengagement upon release of said partial vacuum within said containment.

19. The apparatus as set forth in claim 18 wherein said adhesive is a heat curing adhesive co-mingled with said interengageable means within said containment.

20. The apparatus as set forth in claim 18 wherein said adhesive means is a hot melt adhesive co-mingled with said interengageable means within said containment.

21. The apparatus as set forth in claim 18 wherein said interengageable means and said adhesive means are common integral units comprised of a plurality of discrete particles of adhesive.

22. The apparatus as set forth in claim 17 wherein said interengageable means includes a plurality of solid particles.

23. The apparatus as set forth in claim 22 wherein said solid particles are of a size that they collectively exhibit the character of a volume of powder.

24. The apparatus as set forth in claim 22 wherein said solid particles are of a size that they collectively exhibit the character of a volume of granulated matter.

25. The apparatus as set forth in claim 22 wherein said solid particles are of a size that they collectively exhibit the character of a mass of discrete beads of matter.

26. The apparatus as set forth in claim 22 wherein said plurality of solid particles includes a plurality of discrete styrofoam particles or layers of material.

27. An apparatus for enclosing a selected body portion of a human body comprising:

an enclosing means which is adapted to confront the body portion;

said enclosing means including a flexible portion which is adapted to be formed into closely conforming relation with respect to at least a corresponding adjacent part of the body portion;

first rigidifying means selectively operable to temporarily rigidify said flexible portion to maintain said closely conforming relation of said flexible portions with said corresponding adjacent part of the body portion; and

second rigidifying means operable to maintain the rigidity of said flexible portion in said closely conforming relation with said corresponding adjacent part of the body portion after release of said first rigidifying means.

28. The apparatus as set forth in claim 27 wherein said flexible portion includes a flexible wall means defining a sealed containment and a plurality of interengageable means disposed within said containment.

29. The apparatus as set forth in claim 28 wherein said first rigidifying means includes means for drawing a partial vacuum within said containment to permit ambient air pressure acting on said flexible wall means to move said interengageable means into mutual interengagement.

30. The apparatus as set forth in claim 29 wherein said second rigidifying means includes adhesive means which is effective to maintain said interengageable means in said mutual interengagement upon release of said partial vacuum within said containment.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,222,478

DATED : June 29, 1993

INVENTOR(S) : Eugene N. Scarberry, Patrick M. Handke

It is certified that error appears in the above--identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 5 (column 10, line 50) delete "the."

In claim 17 (column 11, line 64) delete "in" and
substitute -- for --.

Signed and Sealed this
Nineteenth Day of March, 1996

Attest:



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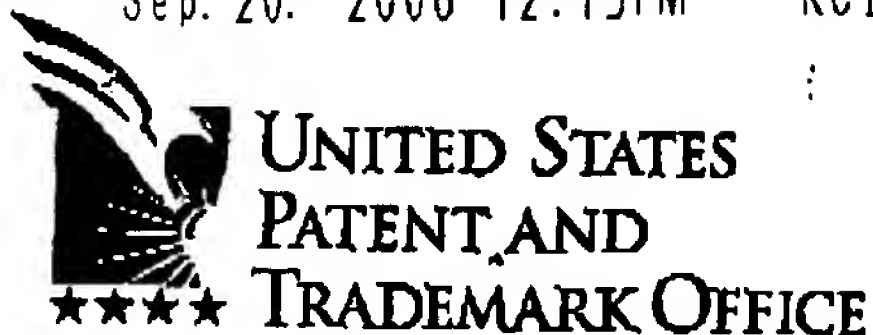
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RECORDATION DATE: 01/13/2003

REEL/FRAME: 013673/0415
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
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DOC DATE: 06/03/2002

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SERIAL NUMBER: 09458280
PATENT NUMBER:

FILING DATE: 12/10/1999
ISSUE DATE:

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4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s) 09/458,280

B. Patent No.(s)

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City: San Antonio State: TX Zip: 78265-9508

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41).....\$ 40.00

☐ Enclosed☒ Authorized to be charged to deposit account

8. Deposit account number:

500326

OFFICE OF PUBLIC RECORDS
2003 JAN 21 AM 8:57
FINANCE SECTION

DO NOT USE THIS SPACE

9. Signature.

Nadeem G. Bridi

Name of Person Signing

Signature

January 13, 2003

Date

1/22/2003 ECUOPER 00000127-500326-09458280 of pages including cover sheet, attachments, and documents: 2

1 FC:8021

40.00 CH

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington, D.C. 20231

PATENT ASSIGNMENT
From Kinetic Concepts, Inc. to KCI Licensing, Inc.

WHEREAS, Kinetic Concepts, Inc. ("Assignor"), a Texas corporation having a principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230, is the owner of U.S. Patent Application No. 09/458,280 for a "Therapeutic Apparatus for Treating Ulcers" (hereinafter "the Patent Application"); and

WHEREAS, KCI Licensing, Inc., a corporation organized under the laws of the State of Delaware, whose address is P.O. Box 659508, San Antonio, Texas 78265-9508 ("Assignee"), is desirous of obtaining the entire right, title and interest in the Patent Application;

NOW THEREFORE, Assignor hereby sells, transfers, conveys and assigns to Assignee the entire right, title and interest in and to the Patent, including all rights to recover for past and/or future infringement, misappropriation, or the like of any and all of said Patent Application, and any continuations, divisionals, continuations-in-part, and international applications that proceed therefrom;

IN TESTIMONY WHEREOF, Assignor hereunto sets its hand and seal this 3rd day of JUNE, 2002.

ASSIGNOR: KINETIC CONCEPTS, INC.

By: *John H. Vrzalik*

Name: John H. Vrzalik

Title: Vice President Research

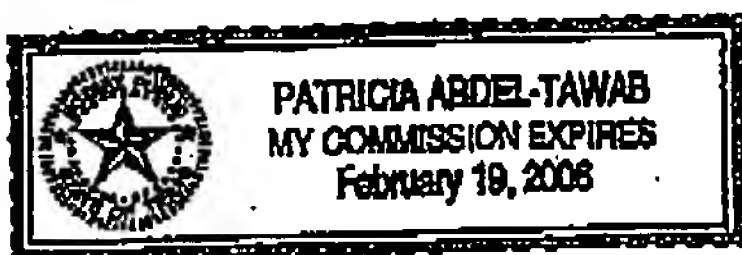
STATE OF TEXAS

§
§
§

COUNTY OF BEXAR

Before me, the undersigned authority, on this day personally appeared John H. Vrzalik, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and consideration therein expressed, and as the act and deed of said Assignor.

Given under my hand and seal of office on this 3rd day of June, 2002.



Patricia Abdel-Tawab
 Notary Public in and for the
 State of Texas

My Commissioner Expires: 2/19/06



received
12-1-03

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOVEMBER 24, 2003

PTAS



102471624A

KINETIC CONCEPTS, INC.
NADEEM G. BRIDI
MANUFACTURING LEGAL DEPARTMENT
P.O. BOX 659508
SAN ANTONIO, TEXAS 78265-9508

**UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT**

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 01/21/2003

REEL/FRAME: 014148/0437

NUMBER OF PAGES: 5

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

VOGEL, RICHARD C.

DOC DATE: 07/30/1997

ASSIGNOR:

TUMEY, DAVID M.

DOC DATE: 07/29/1997

ASSIGNOR:

MORRIS, SUSAN P.

DOC DATE: 07/29/1997

ASSIGNOR:

RANDOLPH, L. TAB

DOC DATE: 07/29/1997

ASSIGNEE:

KINETIC CONCEPTS, INC.
P.O. BOX 659508
SAN ANTONIO, TEXAS 78265-9508

SERIAL NUMBER: 09458280

FILING DATE: 12/10/1999

DOCKET DATE: _____

VAC. 331A.US

DOCKET FOR: _____

PATENT NUMBER:

ISSUE DATE:

014148/0437 PAGE 2

ALLYSON PURNELL, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

Form PTO-1595
(Rev. 10/02)

OMB No. 0651-0027 (exp. 6/30/2005)

Tab settings 

To the Honorable Commission

06-12-2003



102471624

U.S. DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office

ached original documents or copy thereof.

1. Name of conveying party(ies):

Richard C. Vogel

David M. Turney

Susan P. Morris

L. Tab Randolph

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment☐ Merger☐ Security Agreement☐ Change of Name☐ Other _____

Execution Date: 07/29/1997

2. Name and address of receiving party(ies)

Name: Kinetic Concepts, Inc.

Internal Address: 1-71-63

Street Address: P.O. Box 659508

City: San Antonio State: TX Zip: 78265-9508

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s) 09/458,280

B. Patent No.(s) _____

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nadeem G. Bridi

Internal Address: Kinetic Concepts, Inc.

Manufacturing Legal Department

Street Address: P.O. Box 659508

City: San Antonio State: TX Zip: 78265-9508

6. Total number of applications and patents involved: ☐

7. Total fee (37 CFR 3.41).....\$ 40.00

☐ Enclosed☒ Authorized to be charged to deposit account

8. Deposit account number:

500326

DO NOT USE THIS SPACE

9. Signature.

Nadeem G. Bridi

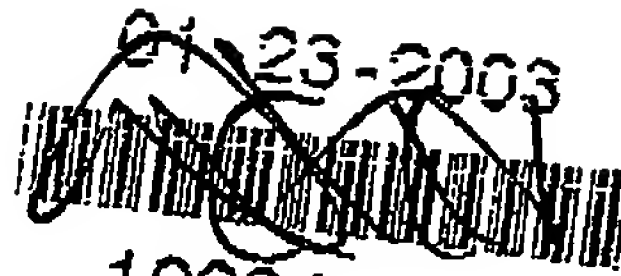
Name of Person Signing

Signature

May 30, 2003

Date

Total number of pages including cover sheet, attachments, and documents: ☐Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington, D.C. 20231

Form PTO-1595
(Rev. 10/02)

RECORD

102345317
PATENTS ONLYU.S. DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office

OMB No. 0651-0027 (exp. 6/30/2005)

Tab settings

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Richard C. Vogel
David M. Turney
Susan P. Morris
L. Tab Randolph

1-21-03

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other

Execution Date: 07/29/1997

2. Name and address of receiving party(ies)

Name: Kinetio Concepts, Inc.

Internal Address:

Street Address: P.O. Box 659508

City: San Antonio State: TX Zip: 78265-9508

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s) 09/458,280

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nadeem G. Bridi

Internal Address: Kinetio Concepts, Inc.

Manufacturing Legal Department

Street Address: P.O. Box 659508

City: San Antonio State: TX Zip: 78265-9508

6. Total number of applications and patents involved: ☐

7. Total fee (37 CFR 3.41).....\$ 40.00

☐ Enclosed☒ Authorized to be charged to deposit account

8. Deposit account number:

500326

DO NOT USE THIS SPACE

01/22/2003 RECEIVED 00000140 500326 09/458280

01 FEB 2003

40.00 CH

Nadeem G. Bridi

Name of Person Signing

Signature

January 13, 2003

Date

Total number of pages including cover sheet, attachments, and documents: 5

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington, D.C. 20231

ASSIGNMENT

WHEREAS, I, Richard C. Vogel, a citizen of the United States, residing at 15614 Mission Crest San Antonio, Texas 78232, (hereinafter referred to as the "Assignor") am an original joint inventor of a certain new and useful THERAPEUTIC METHOD AND APPARATUS FOR TREATING ULCERS for which I have executed an application for Letters Patent of the United States, of even date herewith; and

WHEREAS, Kinetic Concepts, Inc., a corporation organized under the laws of the State of Texas, whose address is P.O. Box 659508, San Antonio, Texas 78265-9508, ("Assignee") is desirous of obtaining the entire right, title and interest in, to and under the said improvements and the said application;

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said Assignor, have sold, assigned, transferred and set over, and by these presents, do hereby sell, assign, transfer and set over, unto the said Assignee, its successors, legal representatives and assigns, my entire right, title and interest in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said Assignee, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND, I hereby covenant that I have full right to convey the entire interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

AND, I hereby further covenant and agree that I will communicate to the said Assignee, its successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and generally do everything possible to aid the said Assignee, its successors, legal representatives and assigns, to obtain and enforce proper patent and similar protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 30th day of July, 1997.


Richard C. Vogel

STATE OF TEXAS

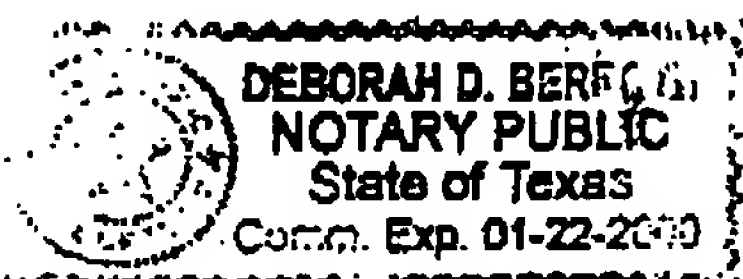
§

§

COUNTY OF BEXAR

§

On this 30th day of July, 1997, before me, a Notary Public in and for the State and County aforesaid, personally appeared RICHARD C. VOGEL, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.




Notary Public in and for the State of Texas

ASSIGNMENT

WHEREAS, I, David M. Tumey, a citizen of the United States, residing at 5018 Newcastle San Antonio, Texas 78249, (hereinafter referred to as the "Assignor") am an original joint inventor of a certain new and useful THERAPEUTIC METHOD AND APPARATUS FOR TREATING ULCERS for which I have executed an application for Letters Patent of the United States, of even date herewith; and

WHEREAS, Kinetic Concepts, Inc., a corporation organized under the laws of the State of Texas, whose address is P.O. Box 659508, San Antonio, Texas 78265-9508, ("Assignee") is desirous of obtaining the entire right, title and interest in, to and under the said improvements and the said application;

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said Assignor, have sold, assigned, transferred and set over, and by these presents, do hereby sell, assign, transfer and set over, unto the said Assignee, its successors, legal representatives and assigns, my entire right, title and interest in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said Assignee, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND, I hereby covenant that I have full right to convey the entire interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

AND, I hereby further covenant and agree that I will communicate to the said Assignee, its successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and generally do everything possible to aid the said Assignee, its successors, legal representatives and assigns, to obtain and enforce proper patent and similar protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 29th day of July, 1997.

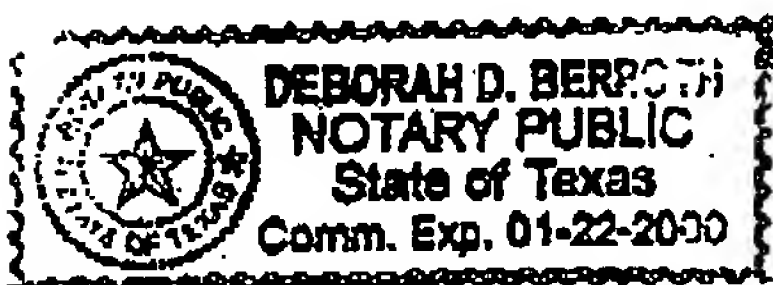

David M. Tumey

STATE OF TEXAS

COUNTY OF BEXAR

On this 29th day of July, 1997, before me, a Notary Public in and for the State and County aforesaid, personally appeared DAVID M. TUMEY, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.


Notary Public in and for the State of Texas



ASSIGNMENT

WHEREAS, I, Susan P. Morris, a citizen of the United States, residing at 2910 Oak Fall San Antonio, Texas 78231, (Hereinafter referred to as the "Assignor") am an original joint inventor of a certain new and useful THERAPEUTIC METHOD AND APPARATUS FOR TREATING ULCERS for which I have executed an application for Letters Patent of the United States, of even date herewith; and

WHEREAS, Kinetic Concepts, Inc., a corporation organized under the laws of the State of Texas, whose address is P.O. Box 659508, San Antonio, Texas 78265-9508, ("Assignee") is desirous of obtaining the entire right, title and interest in, to and under the said improvements and the said application;

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said Assignor, have sold, assigned, transferred and set over, and by these presents, do hereby sell, assign, transfer and set over, unto the said Assignee, its successors, legal representatives and assigns, my entire right, title and interest in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said Assignee, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND, I hereby covenant that I have full right to convey the entire interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

AND, I hereby further covenant and agree that I will communicate to the said Assignee, its successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and generally do everything possible to aid the said Assignee, its successors, legal representatives and assigns, to obtain and enforce proper patent and similar protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 29 day of July, 1997.

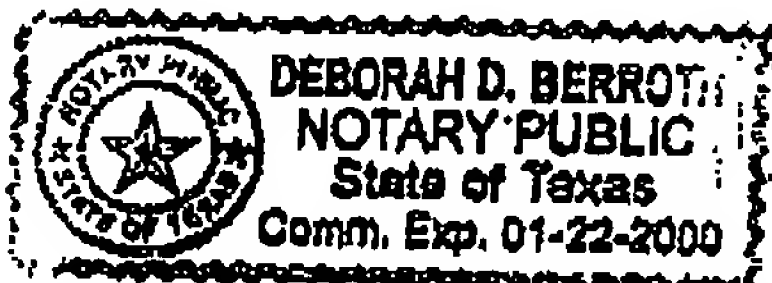
Susan P. Morris

Susan P. Morris

STATE OF TEXAS

COUNTY OF BEXAR

On this 29 day of July, 1997, before me, a Notary Public in and for the State and County aforesaid, personally appeared SUSAN P. MORRIS, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.



Deborah D. Berrot
Notary Public in and for the State of Texas

ASSIGNMENT

WHEREAS, I, L. Tab Randolph, a citizen of the United States, residing at 27917 ~~Fort~~ ^{Bonn LTR 1129/97} Mountain San Antonio, Texas 78260, (Hereinafter referred to as the "Assignor") am an original joint inventor of a certain new and useful THERAPEUTIC METHOD AND APPARATUS FOR TREATING ULCERS for which I have executed an application for Letters Patent of the United States, of even date herewith; and

WHEREAS, Kinetic Concepts, Inc., a corporation organized under the laws of the State of Texas, whose address is P.O. Box 659508, San Antonio, Texas 78265-9508, ("Assignee") is desirous of obtaining the entire right, title and interest in, to and under the said improvements and the said application;

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said Assignor, have sold, assigned, transferred and set over, and by these presents, do hereby sell, assign, transfer and set over, unto the said Assignee, its successors, legal representatives and assigns, my entire right, title and interest in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said Assignee, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND, I hereby covenant that I have full right to convey the entire interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

AND, I hereby further covenant and agree that I will communicate to the said Assignee, its successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths, and generally do everything possible to aid the said Assignee, its successors, legal representatives and assigns, to obtain and enforce proper patent and similar protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 27 day of July, 1997.

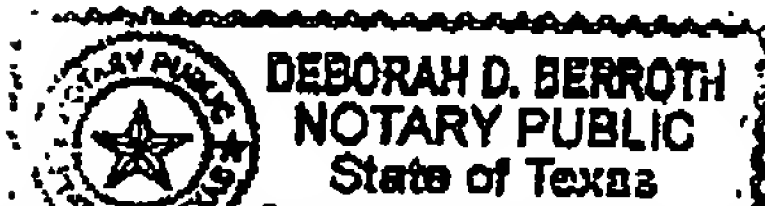

L. Tab Randolph

STATE OF TEXAS

COUNTY OF BEXAR

On this 27th day of July, 1997, before me, a Notary Public in and for the State and County aforesaid, personally appeared L. TAB RANDOLPH, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.


Notary Public in and for the State of Texas



(ReLS6-5/93 Pub.605)

FORM 16-7

16-37

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

MS
~~Box-Assignments~~ **Recordation Services**
~~Commissioner of Patents and Trademarks~~ **Director of the US Patent & Trademark**
~~Washington, D.C. 20231~~ **Office**
P.O. Box 1450, Alexandria, VA

**RESUBMISSION OF ASSIGNMENT (DOCUMENT) PAPERS REFUSED
 FOR RECORDAL (37 CFR 3.51)**

22313-1450

NOTE: "The date of recording of a document is the date the document meeting the requirements for recording set forth in this part is filed in the Office. A document which does not comply with the identification requirements of § 3.21 will not be recorded. Documents not meeting the other requirements for recording, for example, a document submitted without a completed cover sheet or without the required fee, will be returned for correction to the sender where a correspondence address is available. The returned papers, stamped with the original date of receipt by the Office, will be accompanied by a letter which will indicate that if the returned papers are corrected and resubmitted to the Office within the time specified in the letter, the Office will consider the original date of filing of the papers as the date of recording of the document. The certification procedure under either § 1.8 or § 1.10 of this chapter may be used for resubmissions of returned papers to have the benefit of the date of deposit in the United States Postal Service. If the returned papers are not corrected and resubmitted within the specified period, the date of filing of the corrected papers will be considered to be the date of recording of the document. The specified period to resubmit the returned papers will not be extended." 37 CFR 3.51.

"If a document to be recorded is not accompanied by a completed cover sheet, the document and any incomplete cover sheet will be returned pursuant to § 3.51 for proper completion of a cover sheet and resubmission of the document and a completed cover sheet." 37 CFR 3.28.

CERTIFICATE OF MAILING (37 CFR 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

(check and complete appropriate item below):

☒ **37 CFR 1.8(a)**
 with sufficient postage
 as first class mail

or

☐ **37 CFR 1.10**
 as "Express Mail Post Office
 to Addressee" Mailing Label
 No. _____

Date

6/05/03**Nadeem G. Bridi**

(Type or print name of person mailing paper)

(Signature of person mailing paper)

1. The PTO has sent a letter to applicant that the papers previously submitted do not comply with § 3.21 and was not recorded

☒ A copy of the PTO letter is attached

2. The term for resubmission of the papers set in the PTO letter expires

June 22, 2003
(date)

NOTE: The specified period to resubmit the returned papers will not be extended. 37 CFR 3.51 (emphasis added)

3. Applicant resubmits the papers refused recordal:

(check the appropriate box(es) below)

☐ with the necessary corrections and/or omissions entered on the papers

☒ with new appropriate papers added

4. Recordal is now respectfully requested.

Tel. No. (210) 255-4543

Reg. No. 42,361


SIGNATURE OF ATTORNEY

Nadeem G. Bridi

Type or print name of attorney

P.O. Box 659508

P.O. Address

San Antonio, TX 78265-9508

(Resubmission of Assignment Papers Refusal For Recordal [16-7]—page 2 of 2)



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331	8678
30159	7590	11/24/2003		
ATTN: LEGAL-MANUFACTURING KINETIC CONCEPTS, INC. P.O. BOX 659508 SAN ANTONIO, TX 78265-9508				
			EXAMINER DEMILLE, DANTON D	
			ART UNIT 3764	PAPER NUMBER

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

received
12-1-03

PTO-90C (Rev. 10/03)

VAC. 331A
1-24-04-2ND
DOCKET DATE: 2-24-04-3ND
DOCKET FOR: FINAL OA +
DOCKET BY: [Signature] Notice of Appeal

Office Action Summary

Application No.

09/458,280

Applicant(s)

VOGEL ET AL

Examiner

Danton DeMille

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Application/Control Number: 09/458,280
Art Unit: 3764

Page 2

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-5, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al. and Dye.

As noted previously, Jacobs teaches an inflatable foot wrap for applying compressive force over the lower leg and foot of the patient.

Jacobs also teaches that the foot wrap can be used in combination with a wound dressing column 6, lines 4-7. In order to complete the teaching of Jacobs one needs to find a conventional wound dressing. Argenta teaches a conventional wound dressing that uses a porous foam pad 10 positioned within the ulcer, a drape 12 for covering and sealing the ulcer and fluid communication means 11, 15.

Jacobs appears silent with regard to exactly what is used to inflate the inflatable wrap. Jacobs teaches that the interface pressure may be regulated by the amount it is inflated but doesn't disclose how this is done. Dye teaches a conventional pump, reservoir and valves in which to supply pressure to inflation bladders. Dye teaches that the valves are closed while the compressor 32 charges the accumulator 30 with pressurized gas. Next the valve is opened to permit passage of pressurized fluid from the accumulator 30 into the ankle chamber, column 3, lines 28-39.

It would have been obvious to one of ordinary skill in the art to modify Jacobs to use a conventional wound dressing such as taught by Argenta in combination with the foot wrap as suggested by Jacobs and to use automatic positive pressure source as taught by Dye to

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automatically regulate the pressure within the inflatable foot wrap. It appears that applicant has merely taken individual conventional elements and stuck them together.

Claims 6, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Tumey et al. 5,443,440. If one wishes to apply continuous pressure or intermittent pressure a controller and processor would have been an obvious provision. Tumey teaches a controller 44 and processor 70 for controlling the operation of the inflation. It would have been obvious to one of ordinary skill in the art to further modify Jacobs to provide a controller and processor as taught by Tumey to better control the operation of the device.

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 6 above, and further in view of Khouri. Tumey already teaches a pressure sensor 47 for regulating the inflation pressure. Regulating pressures of any kind whether it be positive or negative would be well within the realm of the artisan of ordinary skill. However, Khouri is additionally cited to teach the convention of a pressure sensor 24 in the vacuum environment and wound dressing figure 6. It would have been obvious to one of ordinary skill in the art to further modify Jacobs to include a pressure sensor as taught by Khouri to maintain proper pressure within the application site.

Claims 1-6, 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. in view of Argenta et al. and Tumey et al. 5,840,049.

Tumey '049 alternatively teaches the compressor and reservoir system for maintaining pressure within the bladders. It would have been obvious to one of ordinary skill in the art to modify Jacobs to use a conventional vacuum wound dressing as taught by Argenta in

Application/Control Number: 09/458,280
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Page 4

combination with the foot wrap as suggested by Jacobs and to use a positive pressure source including a compressor, reservoir and controller as taught by Tumey to better control the positive pressure application.

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al., Argenta et al. and Tumey et al. '049 as applied to claim 6 above, and further in view of Khouri. Tumey already teaches a pressure sensor 47 for regulating the inflation pressure. Regulating pressures of any kind whether it be positive or negative would be well within the realm of the artisan of ordinary skill. However, Khouri is additionally cited to teach the convention of a pressure sensor 24 in the vacuum environment and wound dressing figure 6. It would have been obvious to one of ordinary skill in the art to further modify Jacobs to include a pressure sensor as taught by Khouri to maintain proper pressure within the application site.

Double Patenting

Claims 1-6, 8-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,840,049 in view of Argenta et al. and Jacobs et al. Tumey teaches an inflatable foot wrap with a compressor and reservoir as claimed and adding a wound dressing such as taught by Argenta would have been an obvious provision if the injury to the leg requires a wound dressing. Jacobs is additionally cited to teach that the combination of inflatable foot wrap and wound dressing is old. It would have been obvious to one of ordinary skill in the art to modify Tumey to include a vacuum wound dressing as taught by Argenta if the patent so requires and as further suggested by Jacobs.

Claim 7 is rejected under the judicially created doctrine of obviousness-type double

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Page 5

patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,840,049 as set forth above and further in view of Khouri. Tumey already teaches a pressure sensor 47 for regulating the inflation pressure. Regulating pressures of any kind whether it be positive or negative would be well within the realm of the artisan of ordinary skill. However, Khouri is additionally cited to teach the convention of a pressure sensor 24 in the vacuum environment and wound dressing figure 6. It would have been obvious to one of ordinary skill in the art to further modify Tumey to include a vacuum pressure sensor as taught by Khouri to maintain proper pressure within the application site.

Response to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

It is felt that the claims merely recite a combination of conventional elements. The inflatable foot wrap is not new. The vacuum wound dressing is not new. Even the newly claimed compressor and reservoir is not new. Applicant appears to be combining old elements together for a specific intended use. There is no unobviousness to combine these elements together since the prior art even suggests it.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**


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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ddd
20 November, 2003
(703) 308-3713
Fax: (703) 872-9306
danton.demille@uspto.gov


Danton DeMille
Primary Examiner
Art Unit 3764

Notice of References Cited	Application/Control No. 09/458,280	Applicant(s)/Patent Under Reexamination VOGEL ET AL	
	Examiner Danton DeMille	Art Unit 3764	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,840,049	11-1998	Turney et al.	601/149
	B	US-5,007,411	04-1991	Dye, John F.	601/151
	C	US-5,645,081	07-1997	Argenta et al.	602/42
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

30159 7590 12/27/2004
ATTN: LEGAL-MANUFACTURING
KINETIC CONCEPTS, INC.
P.O. BOX 659508
SAN ANTONIO, TX 78265-9508

EXAMINER	
DEMILLE, DANTON D	
ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 12/27/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.A	8678

TITLE OF INVENTION: THERAPEUTIC APPARATUS FOR TREATING ULCERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	03/28/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Page 1 of 3

DOCKET DATE: 3/27/05
DOCKET FOR: *John Lee*
COST. DIV. FILING DATE

PTOL-85 (Rev. 12/04) Approved for use through 04/30/2007.

PAGE 66/93 * RCVD AT 9/20/2006 1:00:12 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/22 * DNIS:2738300 * CSID:210 255 6969 * DURATION (mm-ss):32-14

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Notice of Allowability

Application No.

09/458,280

Applicant(s)

VOGEL ET AL.

Examiner

Art Unit

Danton DeMille

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/17/2004.
2. ☒ The allowed claim(s) is/are 1-17.
3. ☒ The drawings filed on 10 December 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____

Identifying indicia such as the application number (see 37 CFR 1.84(e)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


Danton DeMille
Primary Examiner
Art Unit 3764



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331- <i>fr</i>	8678
30159	7590	12/27/2004		
ATTN: LEGAL-MANUFACTURING KINETIC CONCEPTS, INC. P.O. BOX 659508 SAN ANTONIO, TX 78265-9508				
			EXAMINER DEMILLE, DANTON D	
			ART UNIT 3764	PAPER NUMBER

DATE MAILED: 12/27/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.



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OFFICE OF PETITIONS

In re Application of
Richard C. Vogel, et al.
Application No. 09/458,280
Filed: December 10, 1999
Attorney Docket No. VAC.331.1

ON PETITION

This is a decision on the petition, filed February 14, 2005, under 37 CFR 1.313(c)(2) to withdraw the above-identified application from issue after payment of the issue fee.

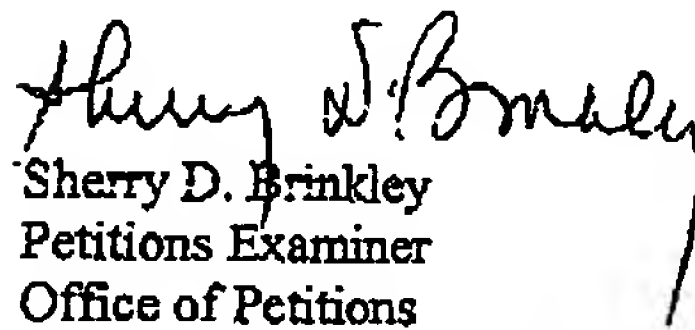
The petition is **GRANTED**.

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

*Petitioner is advised that the issue fee paid on January 21, 2005, in the above-identified application cannot be refunded. If, however, the above-identified application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.*¹

Telephone inquiries relating to this decision should be directed to the undersigned at (571) 272-3204.

The application is being referred to Technology Center AU 3764 for further processing of the request for continued examination under 37 CFR 1.114.


Sherry D. Brinkley
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

DOCKET DATE: _____

DOCKET FOR: _____

DOCKET BY: _____

VAC. 331A-128

¹The request to apply the issue fee to the new Notice may be satisfied by completing and returning the new Issue Fee Transmittal Form PTOL-85(b), which includes the following language thereon: "Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or re-apply any previously paid issue fee to the application identified above." Petitioner is advised that, whether a fee is indicated as being due or not, the Issue Fee Transmittal Form must be completed and timely submitted to avoid abandonment. Note the language in bold text on the first page of the Notice of Allowance and Fee(s) Due (PTOL-85).



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30159 7590 06/01/2005
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P.O. BOX 659508
SAN ANTONIO, TX 78265-9508

EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 06/01/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.1	8678

TITLE OF INVENTION: THERAPEUTIC APPARATUS FOR TREATING ULCERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	09/01/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Page 1 of 3

DOCKET DATE: 9-1-05

DOCKETED: *issue fee due*

PTOL-85 (Rev. 12/04) Approved for use through 04/30/2007.

PAGE 70/93 * RCVD AT 9/20/2006 1:00:12 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/22 * DNIS:2738300 * CSID:210 255 6969 * DURATION (mm-ss):32-14

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.1	8678
30159	7590	06/01/2005		
ATTN: LEGAL-MANUFACTURING KINETIC CONCEPTS, INC. P.O. BOX 659508 SAN ANTONIO, TX 78265-9508			EXAMINER DEMILLE, DANTON D	
			ART UNIT 3764	PAPER NUMBER

DATE MAILED: 06/01/2005

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability

Application No.

09/458,280

Applicant(s)

VOGEL ET AL

Examiner

Art Unit

Danton DeMille

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to IDS filed 2/14/06.
2. ☒ The allowed claim(s) is/are 1-17.
3. ☒ The drawings filed on 10 December 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


Danton DeMille
Primary Examiner
Art Unit: 3764

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

Sheet 1 of 7

Application Number 09/458,280
Filing Date December 10, 1999
First Named Inventor VOGEL, Richard C.
Art Unit 3764
Examiner Name DEMILLE, Danton D.
Attorney Docket Number VAC.331A.US

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OFFICE OF PETITIONS

Examiner Initials*	Cite No. ¹	U. S. PATENT DOCUMENTS			
		Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 1355846	10-19-1920	Rannells	Figs. 1,2
		US- 2547758	04-03-1951	Keeling	Fig. 2
		US- 2632443	03-24-1953	Leshner	Figs. 1-3
		US- 2682873	07-06-1954	Evans et al.	Fig. 2
		US- 2969057	01-24-1961	Simmons	Figs. 1-6
		US- 3367332	02-06-1968	Groves	Figs. 1, 4
		US- 3648692	03-14-1972	Wheeler	Fig. 1
		US- 3682180	08-08-1972	McFarlane	Fig. 3
		US- 3826254	07-30-1974	Mellor	Fig. 2
		US- 4080970	03-28-1978	Miller	Column 1 - Column 3
		US- 4096853	06-27-1978	Weigand	Column 3, Lines 2-20
		US- 4139004	02-13-1979	Gonzalez	Column 4
		US- 4165748	08-28-1979	Johnson	Fig. 2
		US- 4245630	01-20-1981	Lloyd et al.	Fig. 1
		US- 4261363	04-14-1981	Russo	Figs. 1, 4, 5
		US- 4275721	06-30-1981	Olson	Fig. 1
		US- 4284079	08-18-1981	Adair	Fig. 3
		US- 4297995	11-03-1981	Golub	Fig. 1
		US- 4333468	06-08-1982	Geist	Fig. 2, 4

Examiner Initials*	Cite No. ¹	FOREIGN PATENT DOCUMENTS			
		Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)			
		AU-550575-A1	08-26-1982	Wright	P.4, lines 7-10
		EP-0100148	02- 1984	Naylor, et al	Abstract
		WO 96/05873	02-29-1996	Lina	
		WO 97/18007	05-22-1997	Hunt	
		EP-0161865	11-21-1985	Ward	
		EP-0117632-A2	01-1984	JMcCracken	

Examiner Signature

[Signature]

Date Considered

5/31/5

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2

of 7

Complete If Known

Application Number 09/458,280
 Filing Date December 10, 1999
 First Named Inventor VOGEL, Richard C.
 Art Unit 3764
 Examiner Name DEMILLE, Danton D.
 Attorney Docket Number VAC.331A.US

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		Number-Kind Code ² (if known)			
Q		US- 4373519	02-15-1983	Errede et al.	Column 4
		US-			
Q		US- 4392853	07-12-1983	Muto	Fig. 11
Q		US- 4392858	07-12-1983	George et al.	Column 3, Lines 5-58
Q		US- 4419097	12-06-1983	Rowland	Fig. 8
Q		US- 4475909	10-09-1984	Eisenberg	Figs. 1, 3, 6
Q		US- 4480638	11-06-1984	Schmid	Figs. 2, 3
Q		US- 4526166	06-25-1985	Lederc	Column 5-6
Q		US- 4525374	06-25-1985	Vallancourt	
Q		US- 4540412	09-10-1985	Van Overloop	Column 2
Q		US- 4543100	09-24-1985	Brodsky	Fig. 4
Q		US- 4551139	11-05-1985	Plaas et al.	C1, L 66 - C2, L68
Q		US- 4589348	02-11-1986	Hasslinger	C2, L50 - C4, L 27
Q		US- 4605399	08-12-1986	Weston et al.	Fig. 3
Q		US- 4608041	08-26-1986	Nielson	
Q		US- 4640688	02-03-1987	Hauser	Fig. 2
Q		US- 4655754	04-07-1987	Richmond et al.	Column 1, Line 39-44
Q		US- 4733659	03-29-1988	Edenbaum et al.	Fig. 1
Q		US- 4743232	05-10-1988	Kruger	Figs. 2-4

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
Q		PCT/GB98/02743 W099/17793	09-09-1998	KCI Medical Ltd		
Q		AU-745271	03-14-2002	KCI Medical Ltd		
Q		SG-71559	04-16-2002	KCI Medical Ltd		
Q		GB-2,329,127 B	08-16-2000	KCI Medical Ltd		
Q		GB-2,333,965 A	08-11-1999	KCI Medical Ltd		
Q		AU-755396	12-12-2002	KCI Medical Ltd		

Examiner Signature	<i>David J. P. H.</i>	Date Considered	07/11/5
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number 09/458,280
 Filing Date December 10, 1999
 First Named Inventor VOGEL, Richard C.
 Art Unit 3764
 Examiner Name DEMILLE, Danton D.
 Attorney Docket Number VAC.331A.US

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Sheet 3

of 7

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
QR		US- 4787888	11-29-1988	Fox	Figs. 1, 4-6
QR		US- 4826949	05-02-1989	Richmond et al.	Column 1
QR		US- 4838883	06-13-1989	Matsuura	Fig. 7
QR		US- 4840187	06-20-1989	Brazier	Column 2, Line 34-42
QR		US- 4863449	09-05-1989	Therriault et al.	Column 3, Line 45-68
QR		US- 4872450	10-10-1989	Austad	Column 3-4
QR		US- 4878901	11-07-1989	Sachse	
QR		US- 4897081	01-30-1990	Poirier et al.	C3, L25 - C4
QR		US- 4906233	03-06-1990	Moriuchi et al.	Abstract
QR		US- 4906240	03-06-1990	Reed et al.	Fig. 1
QR		US- 4919654	04-24-1990	Kalt	Column 3, Line 8-39
QR		US- 4941882	07-17-1990	Ward et al.	Column 3, Line 38-64
QR		US- 4953565	09-04-1990	Tachibana et al.	Fig. 1
QR		US-			
QR		US- 4985019	01-15-1991	Michelson	Column 1, Line 47-58
QR		US- 5037397	08-06-1991	Kalt et al.	Figs. 1, 2, 4, 6
QR		US- 5100396	03-31-1992	Zamierowski	Figs. 1-10
QR		US-			
QR		US- 5167613	12-01-1992	Karami et al.	Figs. 4-5

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ³ Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁵
QR		GB-692,578	06-10-1953	Minnesota Min..		
QR		WO 80/02182	10-16-1980	Moss, James		
QR		WO/94/20041	09-15-1994	WFU/Argenta, L.		
QR		DE-295 04 378 U1	09-14-1995	MTG		
QR		DE-43 06 478 A1	09-08-1994	Wagner, W.		
QR		CA-2005436	06-30-1990	Kalt, Glenda G.		

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Signature*QR*Date
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 7

Application Number 09/458,280
Filing Date December 10, 1999
First Named Inventor VOGEL, Richard C.
Art Unit 3764
Examiner Name DEMILLE, Danton D.
Attorney Docket Number VAC.331A.US

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		Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Q		US- 5176663	01-05-1993	Svedman et al	C1, L55 - C2, L8
Q		US- 5232453	08-03-1993	Plass et al.	Fig. 2, 5
Q		US- 5261893	11-16-1993	Zamierowski	Figs. 1, 13, 16
Q		US- 5298015	03-29-1994	Komatsuzaki et al.	Abstract
Q		US- 5344415	09-06-1994	Debusk et al.	Column 2, Line 9 -42
Q		US- 5358494	10-25-1994	Svedman	Column 2, Line 34-47
Q		US- 5527293	06-18-1996	Zamierowski	C11, L 62 - C12, L37
Q		US- 5556375	09-17-1996	Ewall	C3, L62 - C4, L65
Q		US- 5607388	03-04-1987	Ewall	Column 3-4
Q		US- 5636643	06-10-1997	Argenta et al.	C6, Lines 18 - 64
Q		US- 5645081	07-08-1997	Argenta et al.	C4, L28 - C5, L22
Q		US- 6071267	06-06-2000	Zamierowski	Figs. 1-3
Q		US- 6135116	10-24-2000	Vogel et al.	Column 9
Q		US- 20020115951 A1	08-22-2002	Norstream et al.	
Q		US- 20020120185 A1	08-29-2002	Johnson	Fig. 3
Q		US- 20020143286 A1	10-03-2002	Tumey	Paragraph 26
Q		US- 6488643	12-03-2002	Tumey et al.	
Q		US- 6493568	12-10-2002	Ball, et al.	
Q		US- 4,233,969	11-18-1980	Lock, et al.	C2, Lines 25 - 53

Examiner Initials*	Cite No. ¹	FOREIGN PATENT DOCUMENTS			
		Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
Q		WO 93/09727	5-27-93	AGENTA	
Q		GB-2 197 789 A	06-02-1988	Smith Industrie	
Q		EP-0358 302	03-14-1990	Smith Industrie	
Q		DE 26 40 413 A1	03 09 1978	Wolf, Richard	

Examiner Signature: *Q. D. Smith* Date Considered: 5/31/05

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 5

of 7

Complete if Known

Application Number	09/458,280
Filing Date	December 10, 1999
First Named Inventor	VOGEL, Richard C.
Art Unit	3764
Examiner Name	DEMILLE, Danton D.
Attorney Docket Number	VAC.331A.US

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		Number-Kind Code ² (if known)			
Q		US- 5,437,622	08-01-1995	Carion, Jean-Pierre	
Q		US- 6,345,623	02-12-2002	Heaton, K., et al	
Q		US- 6,553,998	04-29-2003	Heaton, K., et al	
Q		US- 6,814,079	11-09-2004	Heaton, K., et al	
Q		US- 5,437,651	08-01-1995	Todd, R., et al	
Q		US- 5,549,584	08-27-1996	Gross, James R.	
Q		US- 5,134,994	08-04-1992	Say, Sam L.	
Q		US- 4,710,165	12-01-1987	McNeil, C.B., et al	
Q		US- 3,520,300	07-14-1970	Flower, Guiles	
Q		US- 4,758,220	07-19-1988	Sundblom, L., et al	
Q		US- 5,279,550	01-18-1994	Habib, Magdi, et al	
Q		US- 5,092,858	03-03-1992	Benson C.D., et al	
Q		US- 5,086,170	02-04-1992	Luheshi A., et al	
Q		US- 5,278,100	01-11-1994	Doan, T., et al	
		US-			
		US-			
		US-			
		US-			
		US-			

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

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Signature*W. D. B. H.*Date
Considered

9/3/5

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Filing Date	December 10, 1999
First Named Inventor	VOGEL, Richard C.
Art Unit	3764
Examiner Name	DEMILLE, Danton D.
Attorney Docket Number	VAC.331A.US

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Q		LOUIS C. ARGENTA, MD and MICHAEL J. MORYKWA, PHD; Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience; Annals of Plastic Surgery, ...	
Q		SUSAN MENDEZ-EASTMAN, RN; When Wounds Won't Heal, RN January 1998, Volume 61(1); Medical Economics Company, Inc., Montvale, NJ, USA.	
Q		JAMES H. BLACKBURN, II, MD. et al; Negative-Pressure Dressings as a Bolster for Skin Grafts; Annals of Plastic Surgery, Volume 40, Number 5, May 1998, pages 453-457;	
Q		JOHN MASTERS; Letter to the editor; British Journal of Plastic Surgery, 1998, Volume 51(3), page 267; Elsevier Science/The British Association of Plastic Surgeons, UK	
Q		S.E. GREER, et al; The Use of Subatmospheric Pressure Dressing Therapy to Clos Lymphocutaneous Fistulas of the Groin; British Journal of Plastic Surgery (2000), 53	
Q		GEORGE V. LETSOU, M.D., et al; Stimulation of Adenylate Cyclase Activity in Cultured Endothelial Cells Subjected to Cyclic Stretch; Journal of Cardiovascular Surgery, 31, 1990	
Q		PCT International Search Report; PCT international application PCT/GB98/02713; June 8, 1999	
Q		PCT Written Opinion; PCT international application PCT/GB98/02713; June 8, 1999	
Q		PCT International Examination and Search Report, PCT international application PCT/GB96/02802; Jan. 15, 1998 and April 29, 1997	
Q		PCT Written Opinion, PCT international application PCT/GB/96/02802; September 3, 1997	

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9/3/05

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(Use as many sheets as necessary)

Sheet 7

of

7

Complete If Known

Application Number	09/458,280
Filing Date	December 10, 1999
First Named Inventor	VOGEL, Richard C.
Art Unit	3764
Examiner Name	DEMILLE, Danton D.
Attorney Docket Number	VAC.331A.US

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Q		KOSTYUCHENOK, B.M., et al. ;Vacuum Treatment in the Surgical Management of Purulent Wounds; Vestnik Khirurgi, September 1986	
Q		DAVYDOV, Yu. A., et al; Vacuum Therapy in the Treatment of Purulent Lactation Mastitis; Vestnik Khirurgi, September 1986	
Q		YUSUPOV, Yu. N., et al; Active Wound Drainage, Vestnik Khirurgi, Vol. 138, Issue 4, 1987.	
Q		DAVYDOV, Yu. A., et al; Bacteriological and Cytological Assessment of Vacuum Therapy of Purulent Wounds; Vestnik Khirurgi, October 1988	
Q		DAVYDOV, Yu. A., et al; Concepts For the Clinical-Biological Management of the Wound Process in the Treatment of Purulent Wounds by Means of Vacuum Therapy; Vestnik Khirurgi	
Q		Internation Search Report for PCT international application PCT/GB95/01983; November 23, 1995	
Q		Patent Abstract of Japan; JP4129536; Terumo Corporation; April 30, 1992	

Examiner
Signature*Q. D. D. D.*Date
Considered*Q. D. D. D.*

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,280	12/10/1999	RICHARD C. VOGEL	VAC.331.1	8678
30159	7590	06/23/2006		

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SAN ANTONIO, TX 78265-9508

EXAMINER	
DEMILLE, DANTON D	
ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 06/23/2006

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DOCKET FOR: Reply to Notice Missing File
DOCKET BY: Korda



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Applicant is given a period of **THREE (3) MONTHS** from the mailing date of this notice within which to provide a copy of applicant's record (if any) of all of the correspondence between the Office and applicant for the above-identified application (except for U.S. patent documents), a list of such correspondence, and a statement that the copy is a complete and accurate copy of applicant's record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and whether applicant is aware of any correspondence between the Office and applicant for the above-identified application that is not among applicant's records.

☐ The following paper(s) pertaining to the above-identified application cannot be located after a reasonable search:

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Alternatively, applicant may reply to this notice by producing applicant's record (if any) of all of the correspondence between the Office and the applicant for the above-identified application for the Office to copy (except for U.S. patent documents), and provide a statement that the papers produced by applicant are applicant's complete record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), whether applicant is aware of any correspondence between the Office and the applicant for the above-identified application that is not among applicant's records. Such records must be brought to the Customer Service Center in the Office of Initial Patent Examination (Crystal Plaza 2, 2011 South Clark Place, Arlington, VA 22202).

If applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application (or any copy of the paper(s) listed above), applicant must reply to this notice by providing a statement that applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application.

Failure to reply to this notice in a timely manner will result in abandonment of the above-identified application. The three-month period for reply to this notice may be extended (up to a maximum of six months) under the provisions of 37 CFR 1.136(a). However, failure to reply within this three-month period will result in a reduction of any patent term adjustment. See 37 CFR 1.704(b).

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Christon Brown
571-278-4333

*Att: Carolyn & over TC 3700
RND 8611*

Carolyn Brown
Supervisory Legal Instrument Examiner
Group 3700

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Statement (check the appropriate box):

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- ☐ The copy of the paper(s) listed in the notice under 37 CFR 1.251 is/are a complete and accurate copy of applicant's record of such paper(s).
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Date

Signature

Typed or printed name

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Contents

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06/22/2006		2510	RECONSTRUCTION NOTICE UNDER 37 CFR 1.251 - PE
06/21/2006		LFRECON	RECONSTRUCTION OF FILE - BEGIN
05/08/2006		LFLOST	FILE MARKED LOST
08/31/2005	94	IFEE	ISSUE FEE PAYMENT RECEIVED
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02/14/2005		WPET	WORKFLOW INCOMING PETITION IFW
02/14/2005		BRCE	WORKFLOW - REQUEST FOR RCE - BEGIN
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08/17/2004	121	AP.B	APPEAL BRIEF FILED

08/17/2004		XT/G	REQUEST FOR EXTENSION OF TIME - GRANTED
05/24/2004	120	N/AP	NOTICE OF APPEAL FILED
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11/24/2003	61	MCTFR	MAIL FINAL REJECTION (PTOL - 326)
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12/20/2002	71	ACPA	CONTINUING PROSECUTION APPLICATION - CONTI
12/30/2002		ABN9	DISPOSAL FOR A RCE/CPA/129 (EXPRESS ABANDON)
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08/06/2002	71	A...	RESPONSE AFTER NON-FINAL ACTION
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08/06/2002		PREV	PETITION TO REVIVE APPLICATION - GRANTED
06/17/2002		PET.	PETITION ENTERED
10/22/2001		MABN2	MAIL ABANDONMENT FOR FAILURE TO RESPOND T
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10/22/2001		M327	MISCELLANEOUS COMMUNICATION TO APPLICANT
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01/28/2000	20	OIPE	APPLICATION DISPATCHED FROM OIPE
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FAX: 571-273-3885
FROM: Robert W. Mason DEPARTMENT: Legal
FAX: 210 255 6969 PHONE: 210 255 6271
Message: Re: U.S. Patent Application No. 09/458,380
Filed: 10 December 1999
First Named Inventor: Vogel, Richard C.
Attorney Docket No.: VAC-331A.US
Confirmation No.: 8678

Dear Sir or Madam:

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Robert W. Mason
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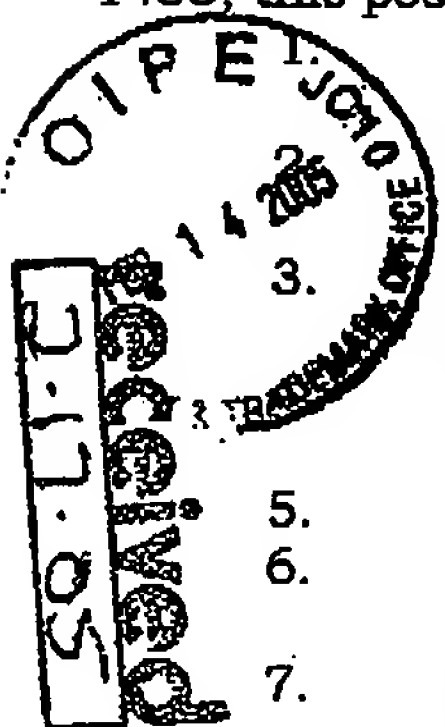
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5. Information Disclosure Statement (1page)
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DEPARTMENT: Legal

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PHONE: 210 255 6271

Message: Re: U.S. Patent Application No. 09/458,280
Filed: December 10, 1999
First Named Inventor: Vogel, Richard C.
Art Unit: 3764
Confirmation No.: 8673
Attorney Docket No.: VAC331A.US

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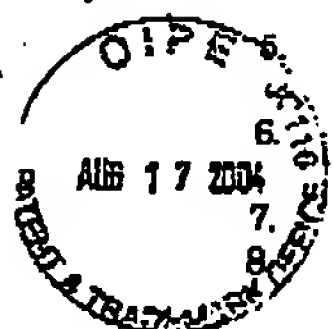
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5. Appeal Brief (33 pages with 5 appendix pages), in triplicate;
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DATE: May 24, 2004

TO: U.S. Patent Office FAX: 782-872-8308

FROM: Eric W. Canyon PHONE: (210) 524-0000

Number of pages including cover sheet: 6

RE: Patent App. No. 09/458,280
Title: THERAPEUTIC APPARATUS FOR TREATING ULCERS
Filed: December 10, 1999
Examiner: Dumile, Dayton
Art Unit: 3764
Docket No.: VAC.458A.US

Enclosed:

1. Transmittal Form (PTO/SB/21);
2. Fee Transmittal in duplicate (PTO/SB/17);
3. Petition for 3 Month Extension of Time (PTO/SB/22); and
4. Notice of Appeal (PTO/SB/31).

Eric W. Canyon

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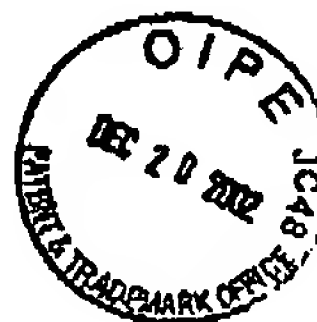
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7. Response to October 4, 2000 Office Action
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